

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

FRED BERGMAN HEALTHCARE
PTY LTD. and SIMAVITA (AUST)
PTY LTD.,

Plaintiffs,

V.

SENECA SENSE TECHNOLOGIES
INC.,

Defendant.

Civil Action No. 1:22-cv-02167

Honorable John Robert Blakley

Jury Trial Requested

JOINT APPENDIX FOR CLAIM CONSTRUCTION BRIEFING

Pursuant to Local Patent Rule 4.2, Plaintiffs Fred Bergman Healthcare Pty Ltd. (“Bergman”) and Simavita (Aust) Pty Ltd. (“Simavita”), and Defendant Seneca Sense Technologies Corporation (“Seneca Sense”), submit this Joint Appendix with the parties’ opening claim construction brief.

Tab	Description	Joint Appendix Page Numbers
A	U.S. Patent No. 7,977,529	JA 0001
B	U.S. Patent No. 7,977,529 File History	JA 0026

Dated: December 10, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that a copy of the foregoing document was served via electronic mail on December 10, 2024 upon all counsel of record.

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US007977529B2

(12) **United States Patent**
Bergman et al.

(10) **Patent No.:** **US 7,977,529 B2**
(45) **Date of Patent:** **Jul. 12, 2011**

(54) **INCONTINENCE MANAGEMENT SYSTEM AND DIAPER**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 823 days.

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(22) Filed: **May 2, 2007**

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A61F 13/15 (2006.01)
G06Q 10/00 (2006.01)

(52) **U.S. Cl.** **604/361**; 604/385.01; 702/177; 702/180; 702/181; 702/188; 702/189; 703/11; 703/16; 703/17; 705/2; 705/3

(58) **Field of Classification Search** 604/361, 604/385.01; 702/177, 180, 181, 188, 189; 703/11, 16, 17; 705/2, 3
See application file for complete search history.

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Primary Examiner — Tatyana Zalukaeva

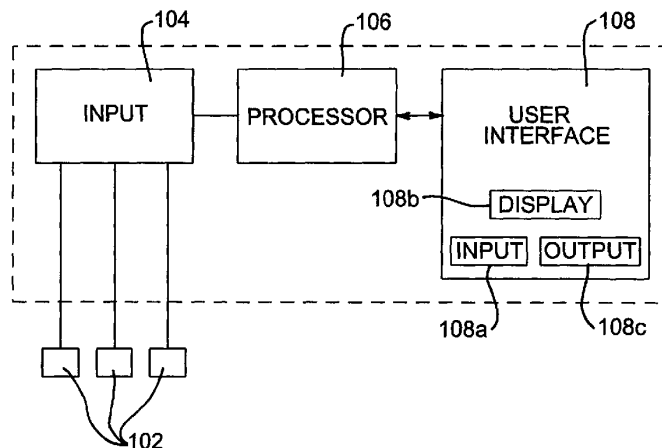
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(57) **ABSTRACT**

An incontinence management system for monitoring wetness in one or more absorbent articles, includes input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article, processor for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article and user interface for communicating with a user of the system. A mathematical model is used to characterise wetness events, receiving as inputs variables derived from sensor signals and optionally, patient and demographic data. The mathematical model can be configured and/or re-configured utilising observation data obtained while monitoring a patient for wetness. A diaper for use with such a system is also disclosed.

61 Claims, 11 Drawing Sheets



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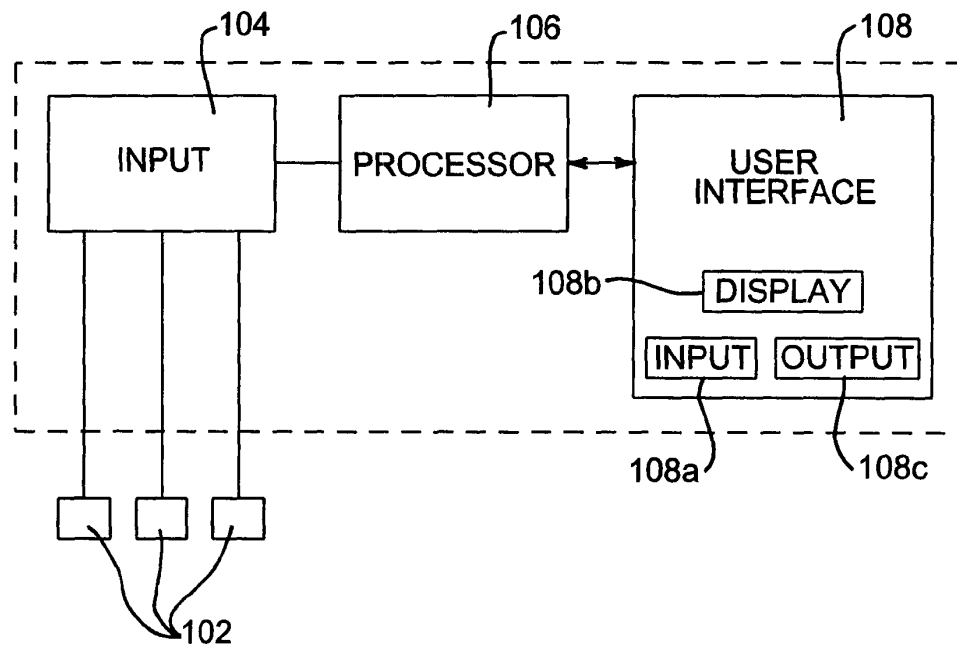


FIG 1

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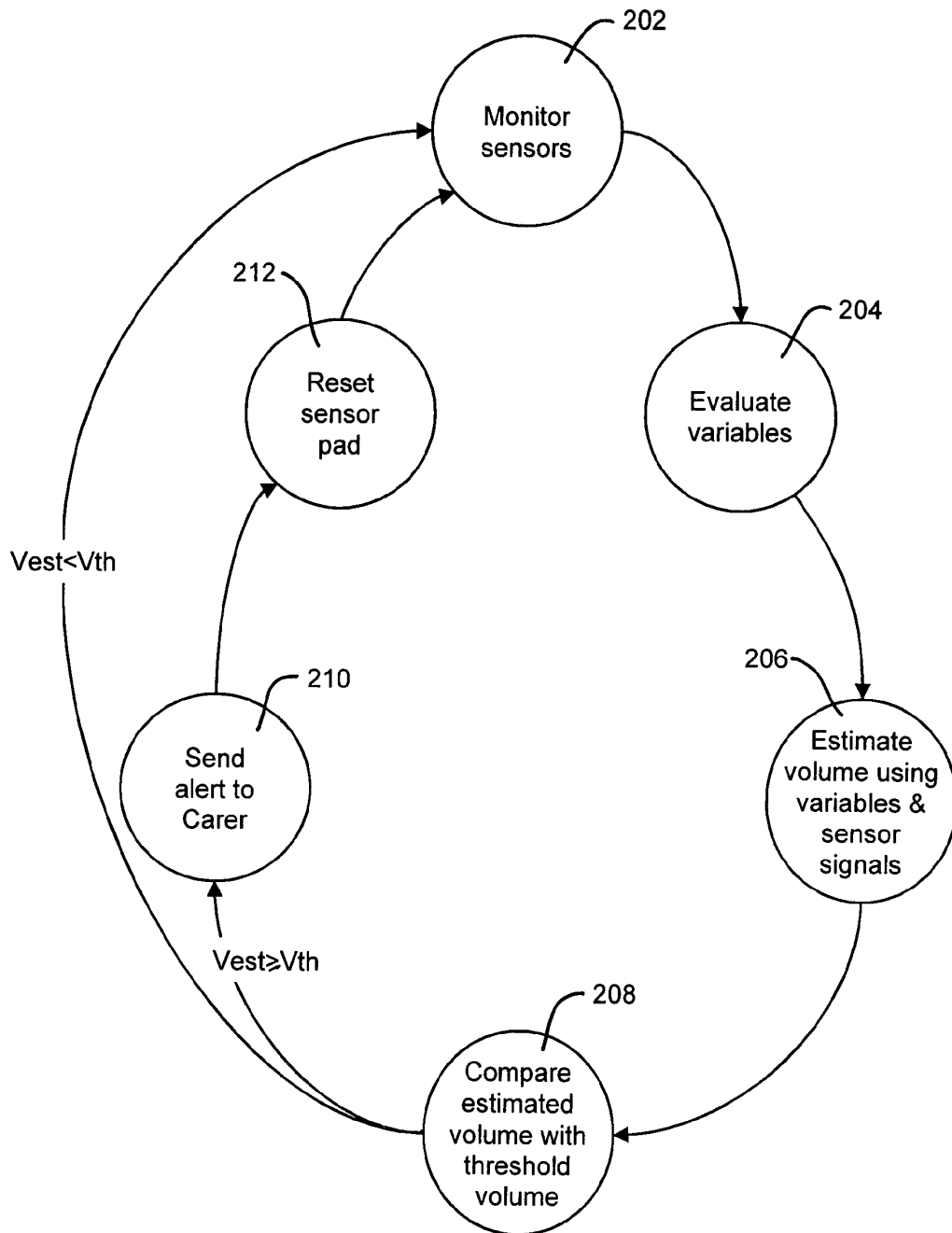


FIG 2

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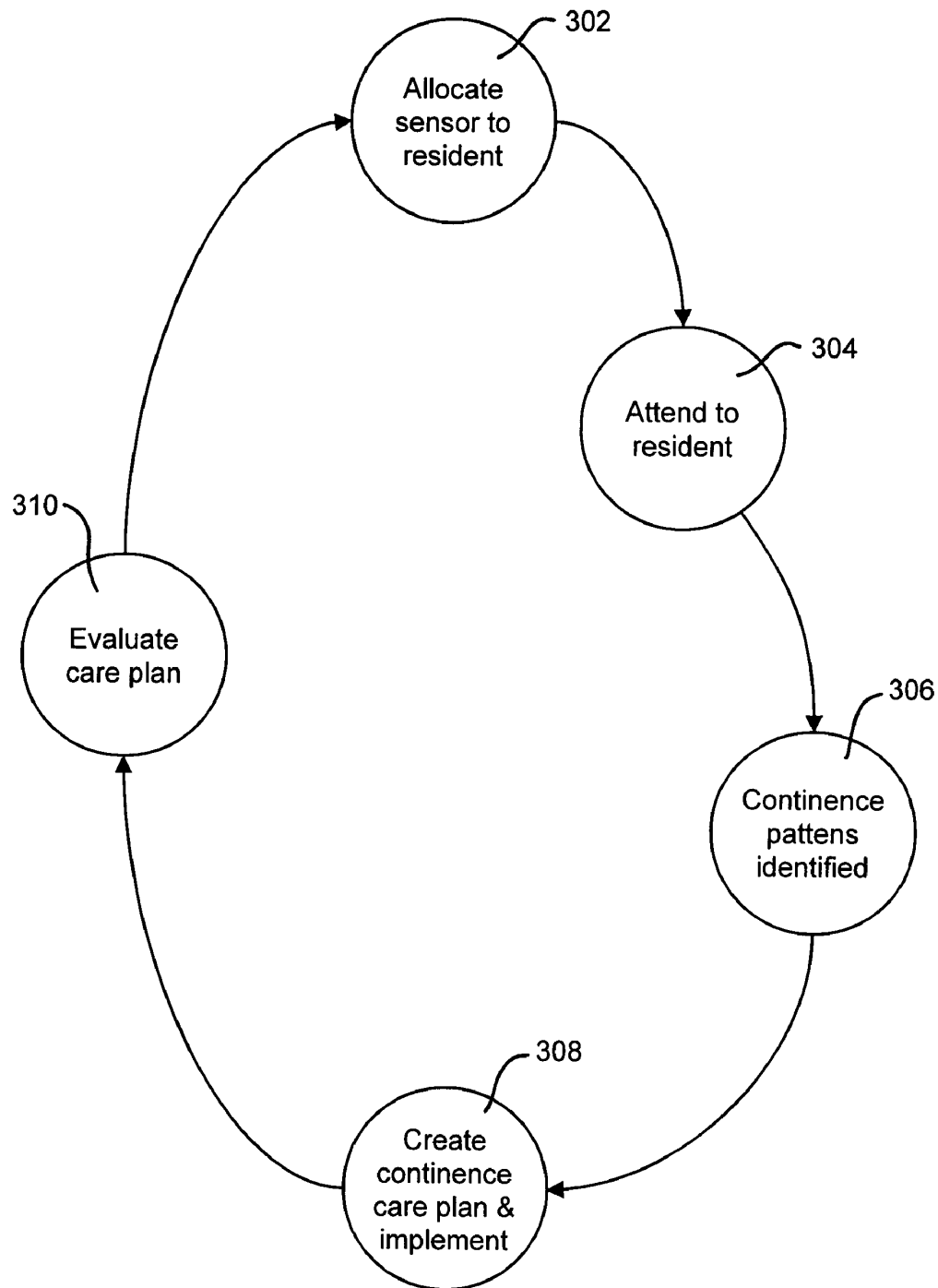


FIG 3

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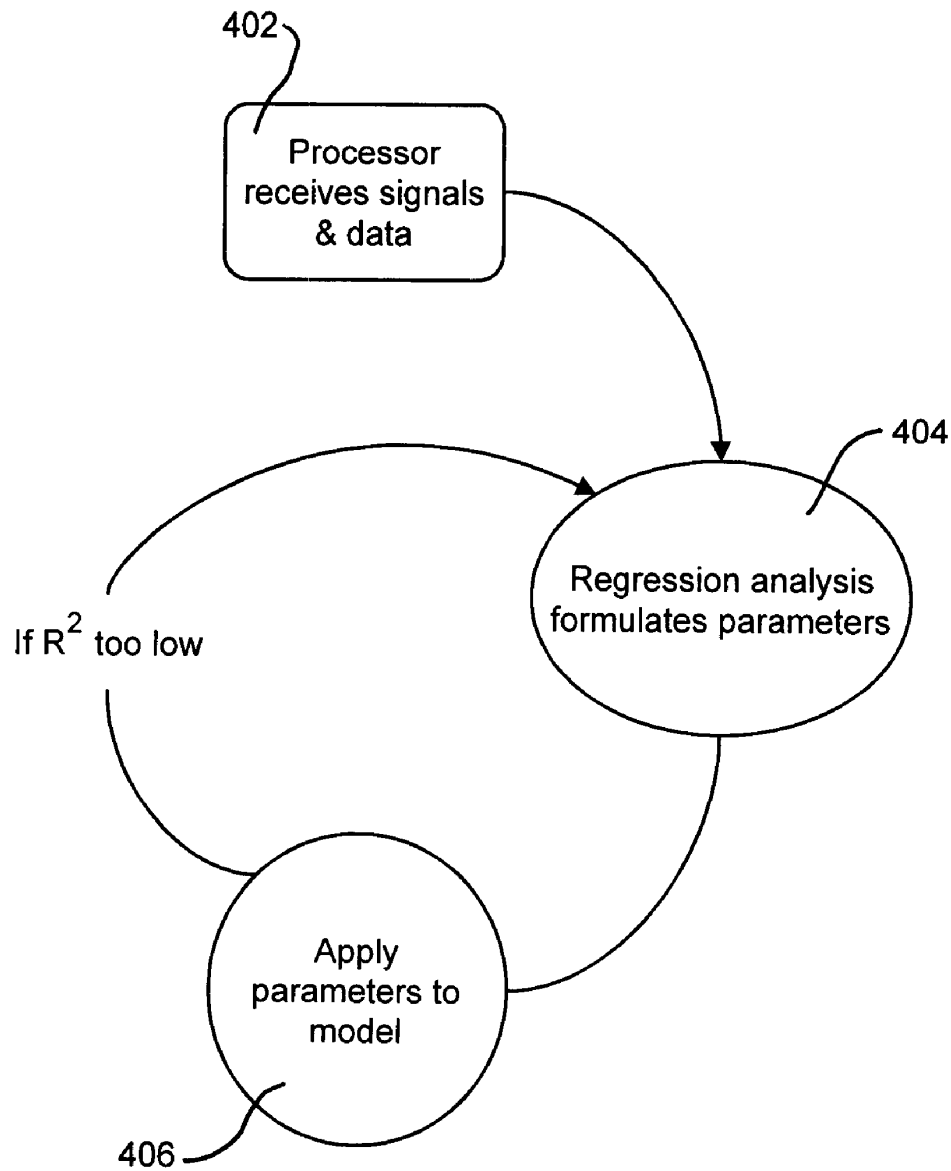


FIG 4

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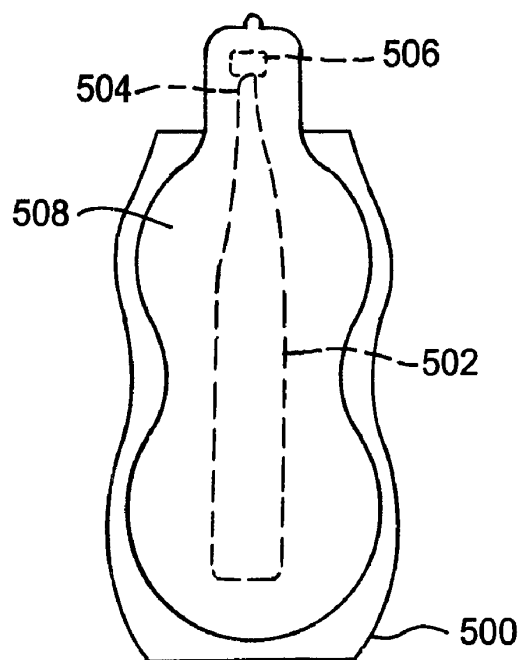


FIG 5a

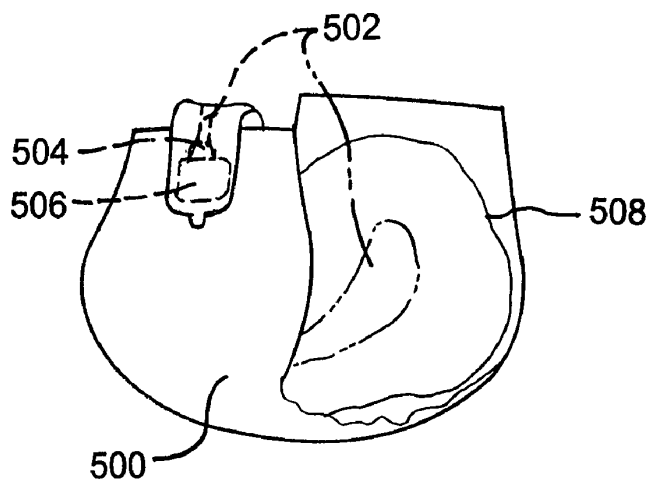


FIG 5b

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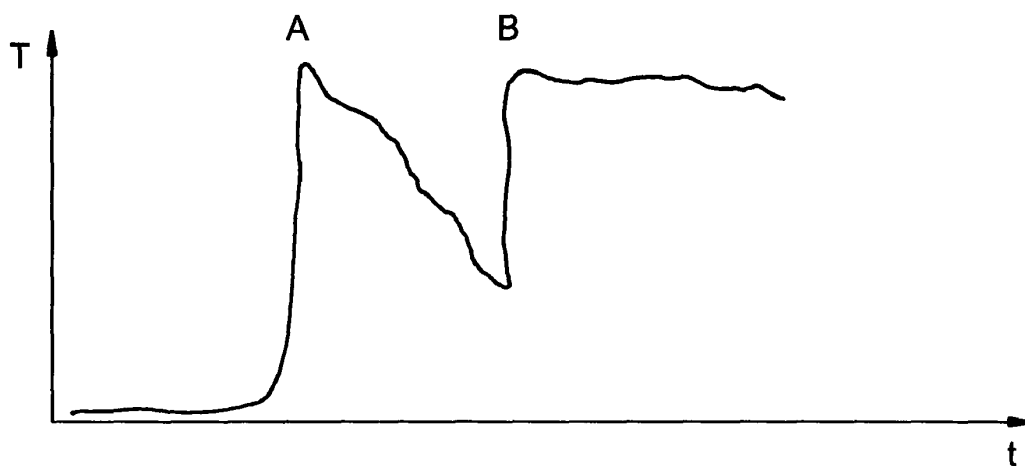


FIG 6

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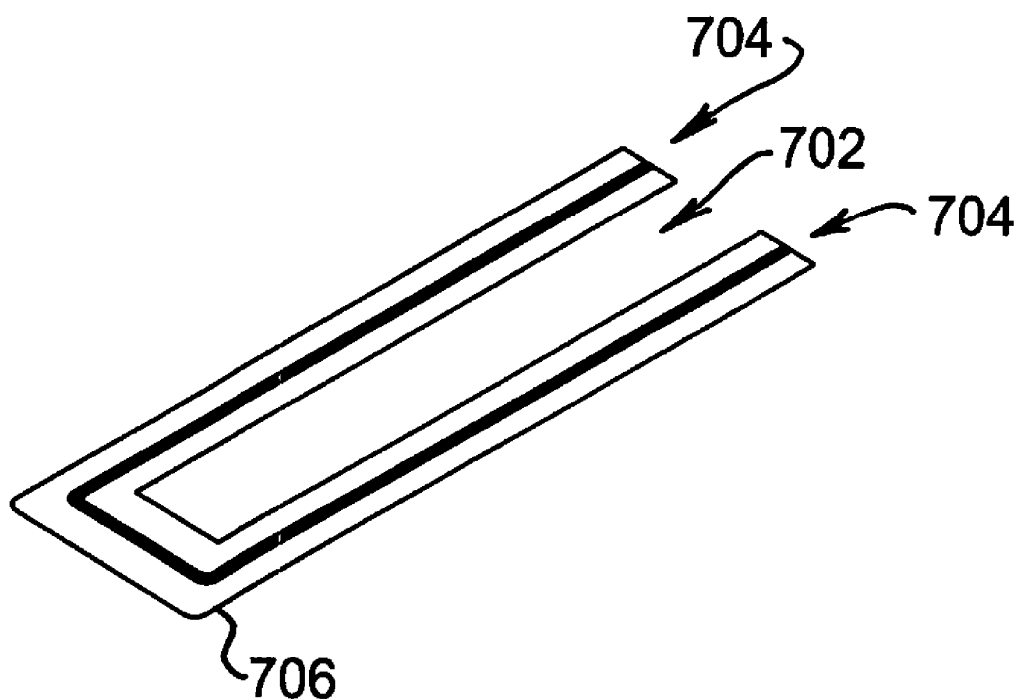


FIG 7

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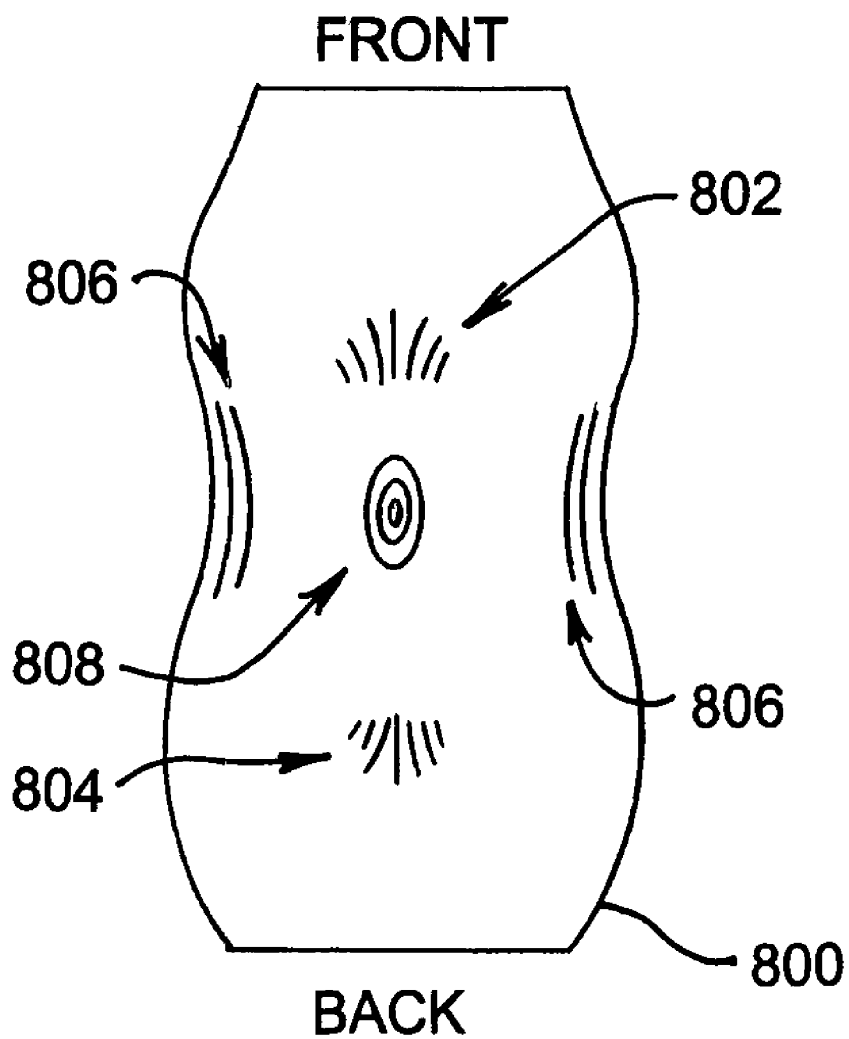


FIG 8

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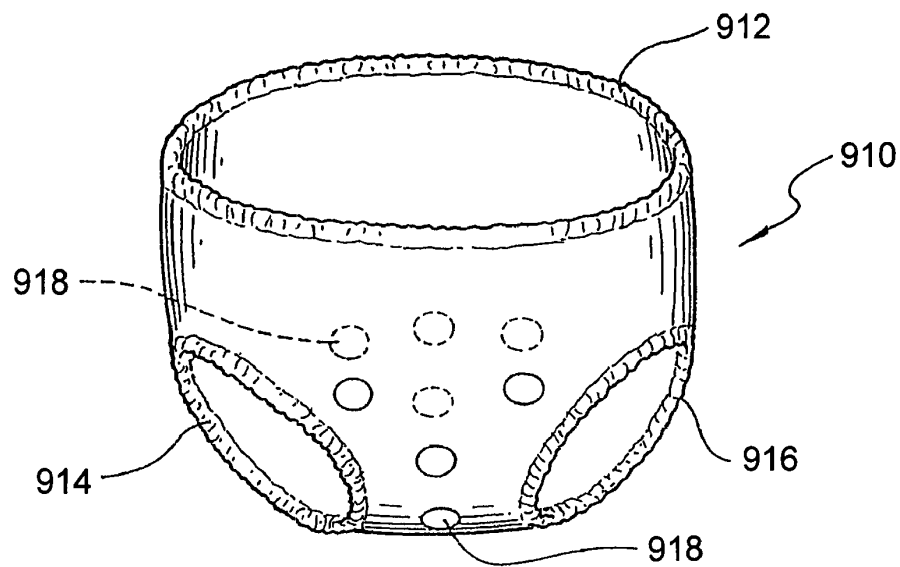


FIG 9

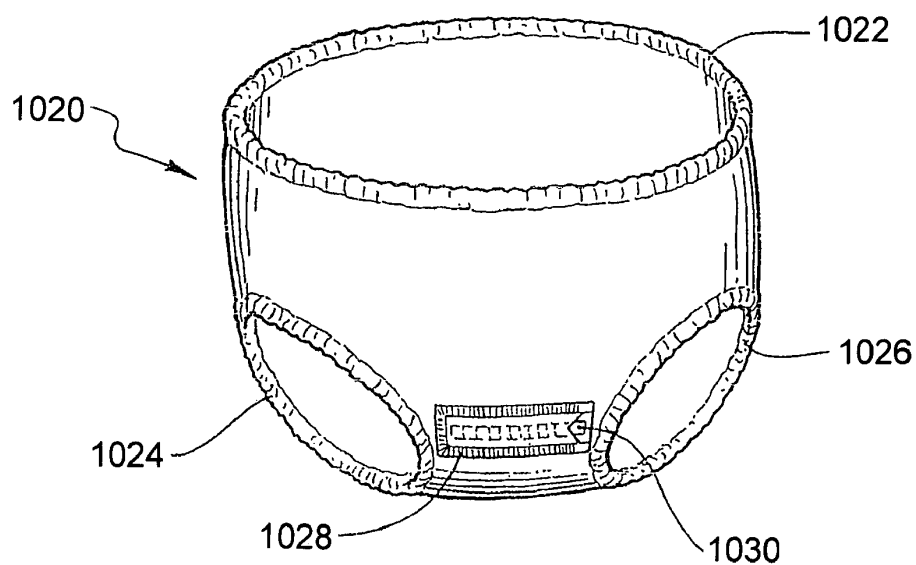


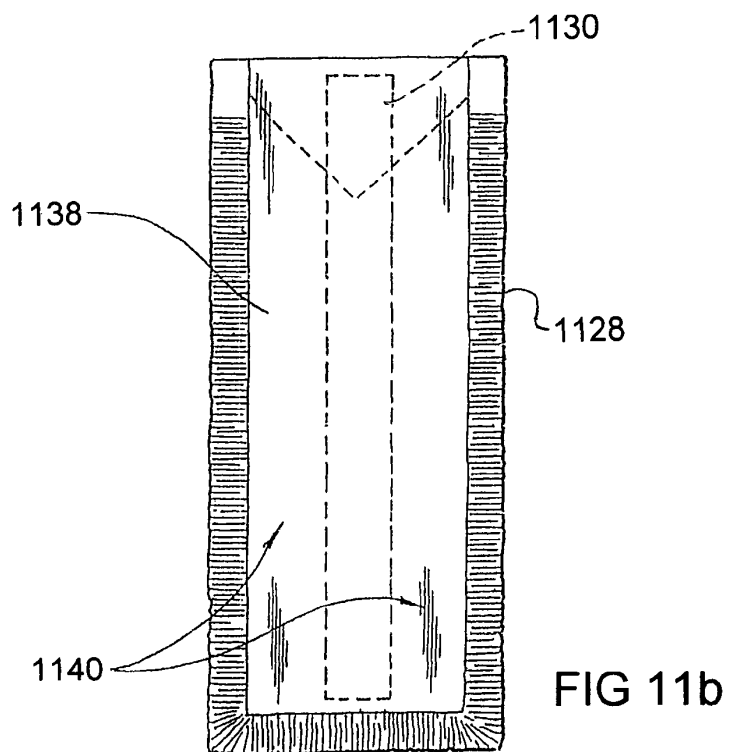
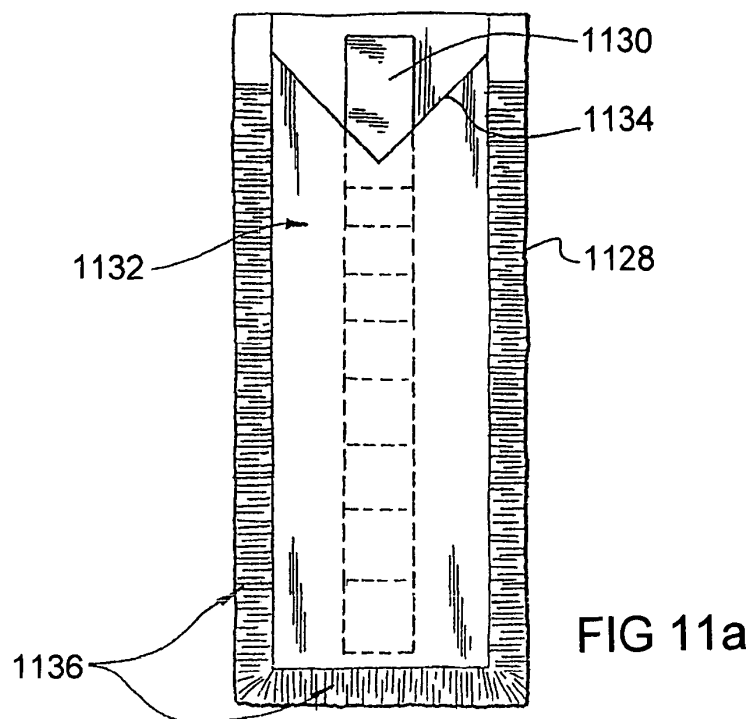
FIG 10

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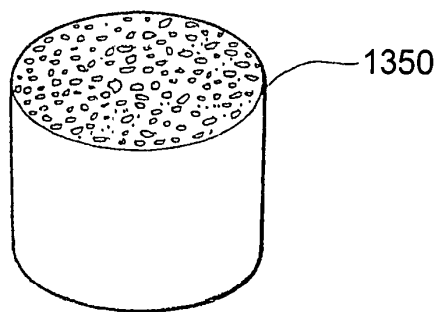
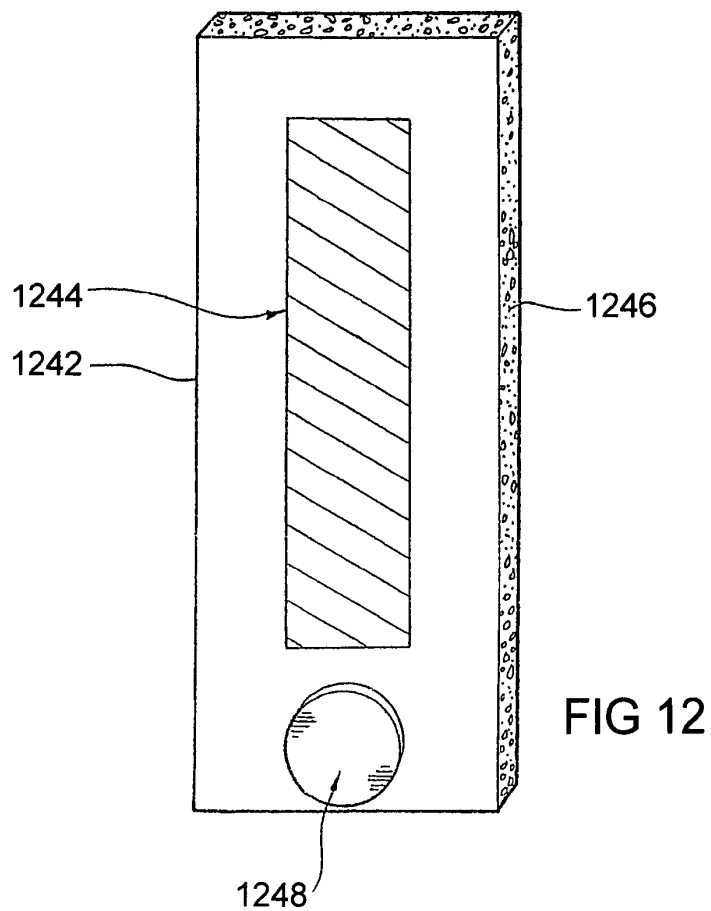


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**INCONTINENCE MANAGEMENT SYSTEM
AND DIAPER**

This is a Continuation-in-Part of PCT/AU2005/001667
filed 28 Oct. 2007 and published in English.

FIELD OF THE INVENTION

The present invention relates to moisture monitoring. It relates particularly but not exclusively to systems, devices and methods for monitoring moisture in absorbent articles such as diapers, incontinence garments, dressings and pads, resulting from wetness events caused by, for example, urinary and/or faecal incontinence. It also relates to a diaper for use with such a system.

BACKGROUND OF THE INVENTION

Incontinence is a condition in which there is uncontrolled release of natural discharges or evacuations. While some forms of incontinence are more widespread, the condition usually affects women, the elderly and the infirm. Urinary incontinence refers to loss of bladder control resulting in involuntary or uncontrolled urination. Other forms of incontinence including faecal or bowel incontinence also exist. In the context of the present application, the term "incontinence" is to be taken to include urinary and faecal incontinence.

Incontinence, in the context of this specification, includes urinary and faecal incontinence, and management of such incontinence is to be seen in the context of persons located in hospitals, nursing homes, aged care facilities, geriatric institutions, private homes and the like.

The aforementioned incontinence, when unchecked, may result in the person suffering from the condition experiencing discomfort or at least embarrassment, and in the existence of unpleasant odours and environment for others in the vicinity of the person. In addition, health regulations or protocols may prescribe a maximum period, such as 15 minutes, for which a patient may be left in a wet state caused by incontinence. In the past, to comply with such requirements, it has been necessary for nursing staff to manually check each patient at least once during the prescribed period. Apart from the unpleasantness experienced by nursing staff in carrying out such manual checks, such a regimen may place a severe strain on staff resources, and may constitute an interruption to patients' rest and sleep.

A range of different incontinence types are recognised. Stress incontinence refers to involuntary loss of urine immediately associated with coughing, sneezing, lifting, straining or other physical exertion. The term "stress" relates to the mechanical stress of the abdominal muscles compressing the bladder wall, working against weakened sphincter muscles. Childbirth, obesity, constipation and changes in the sphincter muscles after the menopause can aggravate stress incontinence as can the use of some drugs.

Urge incontinence refers to the involuntary loss of urine coupled with a strong desire to urinate. Often the sufferer is unable to reach the toilet before there has been a urine loss. The need to visit the toilet may occur very frequently during the day and often at night also. Urge incontinence is generally caused by an overactive or "unstable" bladder which contracts involuntarily in an attempt to empty. The contractions give rise to an urgent desire to pass urine and uncontrolled leakage occurs before a toilet is reached. Mixed Urinary Incontinence (MUI) refers to involuntary leakage associated

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with urge incontinence and also with exertion, effort, sneezing, or coughing associated with stress incontinence.

Overflow incontinence refers to involuntary loss of urine associated with a chronically distended and overfull bladder. The bladder may be distended as a result of incomplete emptying which may be caused by obstruction to the outlet of the bladder or as a result of a failure of the bladder muscle to contract properly. Bladder failure of this kind may be caused by disease of the nervous system, by some drugs or by psychological factors.

Dribble incontinence refers to leakage of urine without warning or provocation. This is a demoralising condition because leakage can occur at anytime and is unpredictable. Persons suffering from dribble incontinence often need to wear protective pads or diapers throughout the day and night. Total incontinence is a term sometimes used to describe continuous leaking of urine, day and night, or periodic large volumes of urine and uncontrollable leaking. Some people have this type of incontinence because they were born with an anatomical defect. It can also be caused by a spinal cord injury or by injury to the urinary system from surgery.

Functional incontinence occurs where the ability to get to the toilet is impaired either by physical conditions such as paralysis or arthritis, or mental impairment. This is very common in nursing home patients who rely on assistance from others for mobility.

Although incontinence is relatively widespread, it is a condition which must be treated with sensitivity as it can be uncomfortable and embarrassing for sufferers and carers alike. When left unchecked, incontinence can become more embarrassing due to the existence of unpleasant odours associated with incontinence events and this can create an unpleasant environment for others in the vicinity of the incontinence sufferer. In addition, exudate escaping the body as the result of an incontinence event often contains bacteria, so unchecked wetness can create health and hygiene problems. Also, health regulations or protocols may prescribe a maximum period, for example 15 minutes, for which a patient suffering incontinence may be left in a wet state.

In the past, to comply with regulations and protocols and to ensure that patients in care institutions such as hospitals, nursing homes, aged care facilities and geriatric institutions are well looked after, it has been necessary for staff to manually check patients suffering from incontinence on a regular basis. Apart from the unpleasantness involved with manual checks, such a regimen also places a strain on staff resources. Often manually checking for wetness will also cause interruption to a patient's rest and sleep.

Incontinence indicators and detection systems exist. However, they have done little to improve the current situation in which carers must manually and regularly check patients for wetness. Existing incontinence detection systems are generally unable to distinguish a urinary incontinence event from a fecal incontinence event or the size of these events. Existing systems are also deficient in that they alarm or alert a carer simply when wetness is detected, with no indication of the degree of wetness present. This can cause more time wasted than saved as very small volumes e.g. of urine or perspiration may trigger an alert even though the patient does not actually require attention from a carer. This can also be a source of embarrassment for the patient.

Some systems involve complicated circuitry and are expensive and difficult to manufacture. Since most diapers and pads are disposable both for efficiency of use and hygiene reasons, complicated sensor systems do not lend themselves to widespread uptake and ongoing use.

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Some systems are clumsy to use and the sensors can interfere with the absorbent capacity of the diaper or pad with which they are used. Others again are generally incompatible with current care practices and actually create additional work, significant complications or changes in care practices 5 undermining any benefits they may offer and making them less susceptible to widespread uptake and ongoing use.

The present invention aims to improve upon these systems, to improve efficiency in monitoring and management of continence with minimal changes in care practices, or at least 10 provide a useful alternative to existing systems.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention, there is 15 provided a moisture monitoring system for monitoring wetness in one or more absorbent articles. The system includes an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article, a processor for processing the one or more sensor signals and for performing 20 an analysis of the signals to characterise wetness events occurring in an absorbent article and a user interface for communicating with a user of the system.

The processor may execute an algorithm to devise automatically a mathematical model for characterising a wetness 25 event in an absorbent article. Alternatively, the processor executes an algorithm to perform the analysis, where the algorithm applies the sensor signals to a pre-determined mathematical model to characterise a wetness event in an absorbent article by determining e.g. an estimated volume of exudate in a wetness event and/or the nature of exudate in a 30 wetness event. Alternatively the algorithm may apply variables derived from the one or more sensor signals to the mathematical model.

The processor may apply sensor signals and/or derive variables 35 from the sensor signals for use by the algorithm to determine one or more parameters suitable for use in a mathematical model for characterising a wetness event. The sensor signals may indicate one or more of conductivity of the exudate, temperature of the exudate, location of the exudate, pH 40 of the exudate, pressure within the absorbent article, odour within the absorbent article, presence of a gas in the absorbent article and presence of blood and/or a biological marker and/or a chemical marker in the exudate.

Variables derived from the sensor signals may be selected 45 from the group including but not limited to area under a sensor signal curve, highest sensor signal value in a predetermined time period, maximum value of a leading edge of the sensor signal, rate of decay of sensor signal after a leading edge, a volume estimated in a previous wetness event, time of 50 onset of a wetness event, time of termination of a wetness event, duration of a wetness event, time of day of a wetness event and time elapsed since last wetness event.

The processor is configured to determine a range of predictions based on patterns identified from sensor signals and/ 55 or using mathematical models. These predictions may include a likelihood of an imminent wetness event, an estimate of when a wetness event is likely to occur, an estimate of a degree of fullness of an absorbent article and/or an estimate of when an absorbent article is likely to reach its absorbent capacity.

Preferably, the user interface includes a wireless transmitter configured to transmit a signal to a user of the system to indicate that a predetermined volume of wetness has been 60 detected in an absorbent article. The processor may also be configured to provide a toileting or voiding diary and/or to derive a toileting or voiding schedule for an individual, based

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on wetness events monitored using the monitoring system, preferably over a number of days.

The system may predict, based on a derived toileting or voiding schedule, when an individual is likely to experience a wetness event which meets pre-defined criteria for manual 5 checking. Further, the system may be adapted to communicate automatically, an alert to a carer when one or more pre-defined criteria for manual checking are satisfied.

In one embodiment, the processor is configured to classify a possible form of incontinence suffered by a patient monitored by the system, such as urinary, fecal, dribble, stress, overflow, urge, mixed urinary (MUI), total and functional incontinence. The processor may also recognise and/or predict 10 lingering wetness in a region of an absorbent article.

The processor may be affixable to a sensor, an absorbent article or to a garment worn by a wearer of an absorbent article. Alternatively, the processor can be incorporated into a central monitoring station adapted to receive sensor signals 15 from a plurality of sensors associated with one or more absorbent articles. A pre-processor may also be associated with a sensor of an absorbent article, locally to the article.

Preferably, the processor is adapted to execute an algorithm to reconfigure one or more mathematical models for use 25 with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type. This may be achieved by, for a training period using the particular individual, the different sensor type or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data, and reconfiguring the mathematical model so that there is 30 satisfactory correlation between the estimates produced using the sensor signals and the reconfigured mathematical model, and the observation data obtained during the training period. Reconfiguring a mathematical model preferably involves employing an algorithm to determine one or more new parameters for the mathematical model e.g. using a linear regression technique.

Observation data includes measurements indicating an amount of wetness in the absorbent article and time of measurement. It may also include demographic information about the patient such as age and gender and patient information such as food and fluid intake and medication regimes.

According to another aspect of the present invention, there is provided a sensor for use with an absorbent article being monitored for wetness. The sensor includes a plurality of sensor elements arranged in a pattern which provides an improved ability to detect wetness. The pattern may involve 50 more sensor elements in regions having higher propensity for variable moisture or temperature, within the absorbent article. The pattern may include sensor elements positioned toward the sides of the absorbent article, near an opening for receiving a leg of the wearer. The pattern may also include sensor elements located at two or more depths of the absorbent article. The sensor pattern includes one or more of elongate sensor elements, sensor elements arranged in a grid and an array of sensor element dots.

In one embodiment, one or more sensor elements extend beyond an edge of the absorbent article, preferably a front edge, and includes a connector for connecting the sensor elements to a signal receiver unit easily without significant disturbance to the patient being monitored.

A cover layer may be provided over the sensor elements which also extends beyond an edge of the absorbent article and includes means such as a pouch, pocket or flap for enclosing a signal receiver unit attachable to one or more of the

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sensor elements. It is preferable that one or more sensor elements are arranged for connection to a signal receiver unit outside the absorbent article.

The signal receiver unit may include storage means for storing sensor signals collected over a period of time. Alternatively or additionally, the signal receiver unit may include means for receiving data relating to a patient's toileting activities e.g. by way of buttons on the device, cable input or contactless communication. The signal receiver unit may also include a transmitter for transmitting sensor signals or variables derived therefrom to a remotely located device.

In one embodiment, the sensor includes a sensor substrate having one or more channels arranged between adjacent sensor elements. Such a sensor is suitable for use with an absorbent article having super absorbent material arranged correspondingly in the article, so as to draw fluid from the one or more channels in the sensor substrate. Preferably, the sensor is provided on a flexible substrate affixable, by adhesive or other means, to an absorbent article wearable by a user.

The sensor elements detect wetness at various identifiable locations with respect to the absorbent article including toward the front of the absorbent article, toward the rear of the absorbent article, toward a side of the absorbent article, and substantially centrally of the absorbent article. Desirably, the pattern of sensor elements facilitates improved detection of moisture from a user in a range of positions including standing, sitting, lying prone, lying supine and lying on the side. Preferably, the sensor elements are also arranged to detect spread of moisture from a wetness event in two or more directions. The sensor may include sensor elements for detecting one or more of electrical conductivity, temperature, pressure, pH, odour, gas and presence of a biological or chemical marker in exudate and location of exudate.

According to another aspect of the present invention, there is provided a method for monitoring moisture in an absorbent article including the steps of receiving one or more sensor signals associated with the absorbent article, the sensor signals indicating wetness in the absorbent article, applying one or more sensor signals to a predetermined mathematical model for characterising a wetness event and, based on the mathematical model, characterising a wetness event in the absorbent article. A method for devising the mathematical model is also disclosed.

Characterising a wetness event preferably involves ascertaining one or more of an estimated volume of exudate in a wetness event and the nature of the exudate although it may also involve determining whether predefined criteria, defined by a mathematical model, have been met. A user may be notified automatically if one or more predetermined notification criteria are met.

Preferably, the algorithm executing the predetermined mathematical model receives as inputs one or more variables derived from the one or more sensor signals and these variables may be derived automatically using a processor as described above. The method may also include maintaining a toileting or voiding diary, being a log of monitored wetness events, also referred to as a bladder chart. A toileting or voiding schedule may also be derived for an individual being monitored, based on wetness events monitored using the monitoring system.

The method may also include predicting, based on a derived toileting or voiding schedule, when an individual is likely experience a wetness event which meets pre-defined criteria for manual checking and this can streamline patient care. The method also facilitates reconfiguring of one or more mathematical models for use with one or more of a particular individual being monitored, a different sensor type and a

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different absorbent article type by, for a training period using the particular individual, the different sensor type and/or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data and reconfiguring the mathematical model so that there is satisfactory correlation between the estimates produced using the sensor signals and the reconfigured mathematical model, and the observation data obtained during the training period. Reconfiguring a mathematical model may involve determining new parameters for the mathematical model e.g. by application of a linear regression algorithm.

Another aspect of the present invention provides a diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper includes a sleeve for the insertion of a diagnostic strip.

In another aspect of the present invention, there is provided a diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper is provided with a plurality of sensors at different locations in said diaper.

In yet another embodiment of the invention, there is provided an incontinence management system or a system for the management of other exudates from the body of a person, characterised by an article adapted to be worn by the person, sensing means associated with said article and adapted to sense a condition, and transmitting means adapted to transmit a signal generated by said sensing means to a location.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will now be described in greater detail with reference to the accompanying drawings. It is to be understood that the particularity of the accompanying drawings does not supersede the generality of the preceding description of the invention.

FIG. 1 is a schematic diagram illustrating features of a moisture monitoring system according to an embodiment of the present invention.

FIG. 2 is a flow diagram showing typical steps in using the monitoring system for continuous monitoring of patients for wetness, using a sensor.

FIG. 3 is a flow diagram showing steps involving use of the invention for care planning.

FIG. 4 is a flow diagram indicating the steps involved with calculating or re-calculating parameters of a mathematical model.

FIGS. 5a and 5b illustrate an example of a sensor used with an absorbent article, according to an embodiment of the present invention.

FIG. 6 represents a sensor signal showing temperature versus time.

FIG. 7 illustrates an embodiment of a sensor having a channel between adjacent sensor elements.

FIG. 8 is a schematic illustration of a diaper or adult incontinence garment showing a pattern of sensor elements according to an embodiment of the invention.

FIG. 9 is a diagrammatic perspective view of a diaper in accordance with one embodiment of the present invention.

FIG. 10 is a diagrammatic perspective view of a diaper in accordance with a second embodiment of the present invention.

FIG. 11a is a front elevation of an embodiment of a sleeve for a diagnostic strip. FIG. 11b is a rear elevation of an embodiment of a sleeve for a diagnostic strip.

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FIG. 12 is a diagrammatic perspective view of a pad for use in a diaper.

FIG. 13 is a diagrammatic perspective view of an alternative pad for use in a diaper.

DETAILED DESCRIPTION

In one aspect, the present invention provides a system for monitoring wetness in one or more absorbent articles such as pads, diapers, adult incontinence garments or the like. Throughout this description, reference will be made to a range of absorbent articles. It is to be understood that the list of absorbent articles identified above is not an exhaustive list and that other absorbent articles and garments are within the scope of the present invention. It is also to be understood that a reference in this specification to any one such article, such as a "diaper" is to be taken to be a reference to any and all other suitable absorbent articles including incontinence garments, pads and the like.

The moisture monitoring system of the invention is generally intended for use in facilities in which staff are required to monitor and care for individuals who suffer from various incontinence conditions. These facilities include hospitals, nursing homes, aged care facilities, geriatric institutions, private homes, respite centres and the like, although it may also be used in other environments e.g. with infants. The system provides useful information to assist users, e.g. carers in the provision of more efficient care to sufferers of incontinence and the like.

As well as the urinary and faecal incontinence and wetness events referred to above, the present invention also has applicability in the detection, monitoring and management of conditions in which other fluids and exudates from the body may be present, including wound management. Thus, as well as the urinary and faecal incontinence, the present invention may be utilised in the management, monitoring and treatment of the production of other bodily fluids and exudates from the body of a patient or resident such as cerebro-spinal fluid (CSF), peritoneal fluid, synovial fluid from joints and bursae around joints, and material discharged from wounds.

Referring now to FIG. 1 there is shown a schematic diagram illustrating features of a moisture monitoring system. The system includes input 104 which receives sensor signals, processor 106 and user interface 108. The system may be used with a plurality of sensors 102 each of which may be associated with a different individual being monitored. The sensor signals received by the input indicate whether moisture is present in an absorbent article being monitored. This may be achieved using a range of different sensor types and arrangements.

In one embodiment, presence of moisture is indicated by an increase in conductivity between spaced electrodes as a result of moisture forming a conductive bridge between them. These sensors could be replaced by or complemented with e.g. thermistor elements in which a change in temperature is indicative of the presence (or absence) of moisture. Conductivity and temperature signals will change with time, as moisture is drawn away from the skin's surface and into the absorbent article.

Alternatively or additionally, the sensor may include sensor elements monitoring other variables which change in the presence or absence of moisture (exudate), or when the volume of exudate changes. These sensor elements may include elements detecting changes in pH, pressure, odour and the presence of gas, blood, a chemical marker or a biological marker in the exudate, or any combination of these. The

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sensor elements may also be arranged in such a way that they convey to the processor the location of moisture detected.

An extensive list of clinically relevant medical conditions may be recognised or suspected by the detection of a number of metabolites, chemicals and ions, as well as other substances and cells of different types, in urine. Such materials as nitrites, amino acids, Beta-2 microglobulin, such measurements as pH, osmolality, white cell count, protein, specific gravity, and such conditions as multiple myeloma and haematuria, may be detected by testing urine from a patient e.g. using a sensor according to an embodiment of the invention.

Processor 106 executes an algorithm to perform an analysis of the sensor signals to characterise wetness events occurring in the absorbent articles being monitored. In one embodiment, the analysis involves modelling a relationship between a dependent variable such as volume of exudate in a wetness event, and sensor signals that can be used to estimate the volume. In one embodiment, the processor executes an algorithm to perform the analysis. Preferably, the algorithm applies variables derived from the sensor signals to the mathematical model to characterise a wetness event.

The algorithm may be programmed in software or in hardware using a range of different techniques and languages known to a person skilled in the relevant art. Advantageously, the algorithm enables the processor to combine different types of data which can be obtained from the sensor signals, and analyse that data to characterise a wetness event, thereby providing more useful information to a user of the system. Moreover, the algorithm enables the system to adapt to new sensor types and new types of absorbent article which have not been used with the moisture monitoring system before.

The processor may be configured to receive data (either entered manually or automatically by, for example, scanning a barcode on a diaper) pertaining to known features of a diaper or incontinence garment being worn by a patient. The features may include the volume, type or brand of the diaper/garment, and the location of the sensors embedded therein. This data enables the processor to identify the type of pad and devise or apply a suitable mathematical model which when used in combination with the data received from the sensor(s) can enable the processor to perform powerful analysis. Because the processor uses wetness and e.g. location data sampled over successive periods; and algorithms using mathematical models to characterise wetness events, it is also able to characterise phantom events or noise, which may result from the patient moving or from intermittent brief interference from other components in the system, and disregard these artefact points.

To characterise the volume of an event, the algorithm applies one or more variables derived from the sensor signals of an individual's absorbent article to a mathematical model which estimates the volume of liquid in the event. The variables derived from the sensor signals may include one or more of: area under a sensor signal curve (e.g. signal magnitude versus time); highest sensor signal value in a predetermined time period; maximum value of a leading edge of the sensor signal; the rate of decay of sensor signal after a leading edge; volume estimated in a previous event; time of onset; time of termination of an event; duration; time of day; and time elapsed since the last detected wetness event; although it is to be understood that this list is not exhaustive.

In addition to volume (or instead of), the algorithm may be adapted to characterise other aspects of wetness events such as the nature of the exudate (i.e. urinary or fecal) and whether a series of wetness events can be classified into a particular type of incontinence such as stress, urge, fecal, overflow, mixed urinary (MUI), dribble, functional and total inconti-

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nence. This can be achieved by applying a suitable mathematical model developed by the same means as the models used to characterise different voiding volumes.

Referring now to FIG. 4, there is shown a flow diagram indicating steps involved in an algorithm calculating and/or recalculating parameters of a mathematical model to characterise wetness events with maximum accuracy and/or to optimise its performance.

For a training period, e.g. 3 days, a patient is monitored for wetness. This may involve continually monitoring sensor signals for indications of wetness and upon every variation in sensor values, obtaining observation data by changing the pad, examining the pad and weighing the pad. Additional observation data may be collected such as amount and time of fluid and food intake, as these variables influence the patient's continence function and are therefore potentially influential variables in the mathematical model.

In a step 402, the collected sensor signals and observation data are received by the processor. In a step 404, the processor executes an algorithm performing a regression analysis to formulate parameters for the mathematical model. In a step 406, these parameters are fed back into the mathematical model and a confidence level is determined which indicates how accurately the mathematical model estimates the actual events defined by the observation data. If the confidence level is acceptable (e.g. above $R^2-0.6$) then the parameters are accepted and the model updated. If the confidence level is too low, a further regression analysis is performed and the confidence level checked again. The algorithm repeats the regression analysis process until an acceptable confidence level is reached.

The same method may be applied to re-calculate parameters of the model. Calculating and recalculating the parameters of the mathematical model utilised by the system is useful for a number of reasons. Firstly, it enables the establishment of an initial mathematical model for predicting particular types of events. Secondly, it allows the system to continually improve the accuracy with which it predicts a patient's continence function and therefore, the efficiency with which care practices can be implemented. Thirdly, by reconfiguring the mathematical model, the system can be adapted to work with different absorbent pads having different absorbent characteristics. In this way, the algorithm can "learn" the characteristics of the pad.

Similarly, the system can adapt to use with additional and/or different sensor types. Again, the ability of the system to "learn" the behaviour of different sensors and sensor elements makes the system adaptable to new products and technologies which will improve accuracy and sensitivity, without the need for a major overhaul of the software employed by the processor. Alternatively/additionally, the processor may re-define one or more mathematical models to suit new sensors, sensor elements or absorbent articles. The need to re-define a mathematical model can be minimised by use of relatively generic code, although this can result in slower calculations.

The moisture monitoring system of the present invention can be used to monitor incontinence sufferers more efficiently than existing systems. FIG. 2 is a flow diagram illustrating typical steps involved in using the monitoring system for continuous monitoring of patients for wetness using sensors. In a step 202, the system monitors sensors applied to absorbent articles worn by patients in a care institution. If a sensor signal value exceeds an initial trigger value, in a step 204 the processor 106 (FIG. 1) derives variables from received sensor signals which, in a step 206 are used as inputs to an algorithm utilising a pre-determined mathematical model to estimate a

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volume of exudate in a wetness event. The mathematical model may be determined using any suitable statistical modelling technique such as regression analysis. In this example, the algorithm applies a mathematical model to estimate volume of exudate using the equation:

$$\text{Volume} = 0.3 \times (\text{Profile_Area}) + 2.4 \times (\text{Patient_Weight}) - 0.6 \times (\text{Patient_Age}) \quad (\text{Eq 1})$$

Profile_Area is the area under a curve of sensor signal versus time for a sensor element monitoring exudate conductivity. Eq 1 gives a confidence factor (R^2) of 0.63. It is to be understood, however, that Eq 1 is just one example of a mathematical model which may be used to characterise wetness events and that other models may be derived with also exhibit a satisfactory level of confidence.

In a step 208 the processor executes an algorithm to compare the estimated volume with a pre-defined threshold level. If the estimated volume is less than the threshold, the processor continues to monitor the sensor signals. If the estimated volume exceeds the threshold amount, then in a step 210 the processor sends an alert to a carer. Once a carer is alerted, the carer attends to the resident and may choose to change the absorbent article and in a step 212, the processor detects that the sensor has been disconnected from the system and resets the sensor data.

The threshold volume used by the processor to alert a carer may be a "qualifying amount" e.g. indicated as small, medium or large or a quantifying amount being a pre-defined volume e.g. 50 ml.

Preferably, the processor may also execute an algorithm to compare the estimated volume with a known estimated capacity of the diaper to give carers an indication of when the diaper is likely to become saturated with exudate so that it can be changed before a saturating wetness event occurs and the patient is made to feel uncomfortable by excess wetness.

The processor may also monitor the total amount of accumulated moisture in a series of wetness events in a single absorbent article and provide an indication to a carer as to when the absorbent capacity of the garment has been or is likely to be reached, to prompt the carer to change the garment for the patient's comfort and wellbeing.

Users may enter data, including patient specific demographic data such as gender, age, height and weight via user interface 108. As indicated in Equation 1 above, these data can also be utilised by the algorithm to estimate e.g. volume. Other entered data may include medical data, i.e. medication, amount of fluid and food intake, details of known conditions, recent surgeries, years in assisted care, years wearing an incontinence garment, continence function if known, and mental condition.

The processor 106 may be incorporated into a central monitoring station such as a nurse's station. The processor may also integrate with or be incorporated into existing nurse call and remote patient monitoring systems controlled at the nurse's station. The processor may also be integrated with other care management systems for streamlining access to non-sensor related data contained within other care management systems such as, for example, fluid and food intake, patient relocation, showering, toileting, surgeries etc.

User interface 108 may also include a transmitter which sends alerts to communication devices such as pagers or nurse phones carried by carers to indicate that there has been a wetness event, or that one is due to occur, or that physical inspection of the patient is required or due. In addition to the detection of wetness events which are estimated to exceed a threshold amount, these conditions warranting physical inspection may include when exudate is fecal in nature or

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when sensors detect blood, a parasite or a biological or chemical marker in the urine or faeces.

FIG. 3 illustrates another use of the invention, where the moisture monitoring system is used in care planning to evaluate and plan the regularity and timing of a carer's manual checking of an individual's continence, and to schedule toileting. The care plan is based on an assessment performed using the monitoring system.

In a step 302, a sensor is allocated to a patient. The sensor has a transmitter unit attached and in a step 304 the patient is monitored for wetness for a continuous period of, for example, 3 to 5 days. During that period, the patient participates in usual activities and the patient is physically checked for wetness by a carer regularly, e.g. every hour. When a sensor signal received by the processor indicates a presence of exudate, an alert is sent to a carer who attends to the patient, changing the pad. Each time the carer checks or attends to the patient, observation data is recorded which includes the nature and amount of exudate (e.g. volume or mass obtained by weighing a soiled pad) and the time of observation.

In a step 306, observation data is used, along with a log of the sensor signals received at the input, to identify patterns in the patient's continence activity. In a step 308 the processor derives automatically, using an algorithm employing another mathematical model, a continence care plan based on the pattern, i.e. frequency and repetition of monitored events. The care plan includes a voiding or toileting schedule which statistically predicts wetness events based on the observed pattern. This is used by carers to plan the regularity (e.g. times of day) that a patient is to be manually checked for wetness and/or assisted with toileting and to plan when to empty the bladder or bowel, prior to periods in which a patient is known to have a pattern of incontinence events. Normal care of the patient can then take place without the need to continually monitor using a sensor.

The voiding schedule anticipates when a wetness event is statistically likely to occur and this can be used to automatically generate an audible and/or visible alert for a carer (e.g. presented on a screen of the user interface 108 or transmitted to a pager or the like) to attend to the patient by assisting with manual toileting or to change the patient's incontinence garment.

It is recommended that the toileting/voiding schedule is re-evaluated periodically (step 310) to maintain its accuracy, in keeping with changes in the patient's continence patterns. Re-evaluation may take place for example every 3, 6 or 12 months, or whenever actual wetness events do not correspond well with those anticipated by the voiding schedule.

In another use of the invention, the moisture monitoring system includes a log for recording wetness events detected by sensors including the volume, time and nature (urinary and/or fecal) of each event. These data are used to produce a bladder diary. These data may also be combined with details entered e.g. at the user interface 108 which relate to food and fluid intake (amount, kind and time), toileting and also any particular activities that the patient has undertaken.

The log may manifest in a memory device in communication or integrated with the processor. The processor may be located centrally and receive sensor signals relating indicative of wetness of a number of absorbent articles worn by different patients. Alternatively, there may be a pre-processor executing the algorithm located near the sensor, on the absorbent article. That is, the sensor and the part of the processor performing the analysis may be a provided together with the sensor. In such arrangement, the pre-processor may also

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incorporate a transmitter for transmitting data from the pre-processor to e.g. a central monitoring system which may include a display.

Referring now to FIGS. 5a and 5b, there is shown a schematic diagram of a sensor 502 according to an embodiment of the invention, applied to an absorbent article 500. The sensor 502 has a sensor element (shown in broken lines) which exhibits a change in conductivity when moisture is present, although other variables such as temperature could be used to detect moisture, as indicated in FIG. 6.

FIG. 6 is a graph of temperature versus time. The rise in temperature at point A is indicative of a wetness event and the rate of decline indicates that the temperature moisture is being drawn away from the sensor element, into the absorbent article. The second leading edge peaking at point B indicates the occurrence of a second wetness event and the signal is sustained. This is typically indicative of a situation in which the absorbent article must be changed e.g. because of the size of the wetness event, because the article has reached its absorbent capacity, or a fecal event has occurred in which the exudate cannot be drawn into the absorbent layers of the article.

Returning to FIGS. 5a and 5b, an embodiment of the invention is shown in which the sensor elements 502 extend beyond a front edge of the absorbent article 500. In this arrangement, a connector 504 is also provided to which a signal receiver unit 506 may be attached. The signal receiver unit may consist of a storage component which records the time and magnitude of sensor signals. Alternatively/additionally, it may include a transmitter which conveys the time and magnitude of sensor signals to a remotely located processor. Alternatively/additionally, the signal receiver unit may include a pre-processor for executing an algorithm performing analysis of the sensor signals which are then stored locally for downloading and/or transmitted to a remote processor which conveys alerts to carers, formulates bladder diaries, voiding schedules or the like. In such arrangement, the signal receiver unit (i.e. pre-processor) may also include means for receiving data relating to a patient's toileting activities. The data may be received wirelessly via a contactless communication device, by a cable connection to an input device or other suitable means for example buttons or the like on the signal receiver unit itself, worn by the patient.

Preferably, signal receiver units 506 are re-useable, and are releasably connectable to the sensors via connectors 504. This connection may utilise any suitable connection means such as a male-female dual-in-line (DIL) connector or the like, as would be known to a person skilled in the relevant art. The signal receiver units may be attached to an absorbent article or to clothing worn by a patient in a manner which is comfortable for the patient to wear, and is also sufficiently robust to minimise the risk of damage or removal while in use. When the diaper/incontinence garment is changed, the signal receiver unit may be disconnected from the soiled sensor, cleaned and attached to a sensor on a new diaper/incontinence garment.

Alternatively, the signal receiver units and sensors may be disposable and incorporated into a diaper or absorbent article during manufacture. In this arrangement, the signal receiver unit may not be visible so the sensor may be activated by a switch or button which is felt through the layers of the diaper. Alternatively, a radio-frequency or other contactless system may be used to activate the device and/or transmit sensor signals to a central monitoring station. In a further alternative embodiment, all parts of the monitoring system are re-use-

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able, although this may create hygiene problems and be undesirable for individuals left with the task of cleaning the components.

In the embodiments illustrated in FIGS. 5a and 5b, a cover layer 508 is provided over the sensor elements. In regions of the cover layer affected by exudate, it is preferred that the cover layer material is liquid permeable so that any moisture resulting from a wetness event can be drawn into the absorbent layers of garment 500. In a preferred embodiment, a flap or pouch is provided to contain the signal receiver unit (which may also provide a transmitting/pre-processing/memory functions). The flap or pouch may be provided by a portion 508a of the cover layer which extends beyond and folds over the front edge of the absorbent article and can be fastened in place by adhesive, Velcro® or other means. The flap or pouch deters individuals, particularly those with forms of dementia or mental illness from tampering with the unit. Preferably, the sensor and absorbent article are arranged in such a way that the signal receiver unit is attachable thereto outside the absorbent article.

The processor and other components which are located on the diaper (e.g. transmitter, pre-processor) may be powered by a small battery or electronic component storing energy. Alternatively, the sensor may include or be part of an RFID or other passive device. To conserve power, the transmitter/pre-processor may deactivate when there has been no wetness event for a predetermined length of time. The devices may be reactivated when a wetness event occurs.

The processor analyses signals received from the sensors to characterise wetness events which are detected for each patient. Characterisation of wetness events by the processor may include characterising the cause of a wetness event by making a distinction between wetness resulting from incontinence, perspiration or other leakage or discharge which may occur due to bedsores or decubitous ulcers which can develop in immobile patients.

A sensor 102 may be incorporated into a pad, diaper or adult incontinence garment when manufactured, or it may be provided separately and attached to an "off the shelf" diaper by way of adhesive or other fixation means. For the latter, sensor elements are provided on a substrate which may be liquid permeable so that exudate released by the wearer passes through the substrate (activating the sensor elements) and is drawn away from the user into the absorbent layers of the diaper. One or more pores and/or channels may be provided in the sensor substrate to facilitate drawing of exudate away from the skin surface into the diaper. FIG. 7 illustrates one such embodiment, where there is an elongate channel 702 provided between two elongate sensing elements 704 on a substrate 706 of a sensor. It may be desirable to use a sensor having a substrate of this kind with an absorbent article with super absorbent material correspondingly arranged in the article so as to draw fluid from the one or more channels in the sensor substrate into the absorbent layers and away from the wearer.

In one embodiment, sensors 102 are conductive elements. When an electrolyte such as urine contacts the conductive elements in sufficient quantity, a conductive bridge is formed between the elements and this can be detected by monitoring one or more electrical characteristics of the elements such as resistance or conductance, capacitance or the like. The conductive elements may be formed using any suitable conductive materials or combinations of materials including gold, copper, silver, conductive inks, polymers, tapes, resins and threads, other suitable conductive polymeric materials, conductive film, fibres or electrodes including, for example, an inert metal. Alternatively/additionally, the sensor elements

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may detect changes in temperature, pH odour, gas, or the presence of blood or a chemical or biological marker in exudate to indicate a presence of moisture.

Production of the sensor may utilise a range of manufacturing methodologies. One example is screen printing or etching which can be employed to deposit the sensing elements on a suitable substrate. In one form, the sensor may be provided in the form of a flexible printed circuit board formed on a Mylar or other suitable flexible substrate. For three-dimensional arrays, the sensor elements may be deposited on a number of substrate layers which are then bonded into a multilayer liner. For sensor elements incorporated into diapers, depositing the layers on the various absorbent layers of the diaper can be integrated into the diaper manufacturing process.

The sensor elements may be elongate or provided in the form of grids, dots or the like, arranged in a pattern along and/or in the diaper or a pad or liner attachable thereto. By utilising, for example, screen printing or etching techniques, effective patterns can be designed and printed in layers of the sensor quickly and accurately. Advantageously, screen printing can deposit conductive polymers, inks and the like in very fine lines or grids between which exudate including urine and faeces may be absorbed into deeper, more absorbent layers. This enables conductive elements of a sensor to be incorporated into a diaper or absorbent article without significantly affecting the performance of the diaper.

The sensor elements are preferably provided in a quantity and pattern sufficient to enable detection of moisture in different locations in an absorbent article being worn by a user. The pattern may be a two-dimensional pattern in which sensor elements are provided in a single layer or in a three-dimensional pattern. The pattern of sensor elements is preferably such that the elements are focussed in regions of the article where there is a greater likelihood of them being affected by a wetness event. FIG. 8 is a schematic drawing of a diaper 800 laid flat, showing one example of a pattern of sensor elements which may be suitable. Each of the sensor elements may be uniquely identified enabling sensor signals to convey to the processor data indicating that wetness is present, as well as the location of the sensor element(s) detecting the wetness. This enables the processor to determine where in the absorbent article and the extent to which the wetness has occurred. Spread of wetness may also be identified.

In one embodiment, the sensor has a plurality of layers and the sensor elements are arranged in a three-dimensional pattern within the layers. A three-dimensional array is advantageous for a number of reasons. Firstly, absorbent articles such as diapers are flexible in nature and therefore prone to folding or scrunching particularly in regions around the legs. To circumvent a problem in which 2 or more conductive elements of a sensor are caused to "short" together as a result of a fold in the article or movement of a wearer, adjacent conductive elements may be placed in alternate layers of the sensor, separated by an electrically insulating permeable layer to prevent shorting in the absence of wetness.

Secondly, by positioning sensor elements in different layers, it is possible for the sensor to convey additional location data to the processor relating to the depth at which moisture is detected. This is particularly important for sophisticated diapers and incontinence garments which are multi-layered in their construction and designed with super absorbent and "wicking" properties to draw wetness away from the wearer and direct it to chambers or zones in the absorbent layers where it is retained. Positioning sensor elements in or near various absorbent layers of the article can convey further

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relevant data to the processor which may relate to, for example, the degree of wetness (or fullness) of a storage chamber within a diaper. Also, elements located at various depths allow the system to monitor the absorption of fluid into a diaper. Thus, the sensor will not require 'pooling' of moisture to detect wetness. This is especially useful in view of the fact that most modern absorbent garments are manufactured to maximise the absorption of liquid away from the skin.

As indicated above, the sensor elements are arranged in a pattern which maximises the ability to detect relevant data, for use in characterising wetness events. For example, as illustrated in FIG. 8, the pattern may provide sensor elements more densely in a region toward the front of the absorbent article (802), to the rear of the absorbent article (804), and around the leg openings (806) and in the centre, between the leg opening (808), where liquid is likely to drain. Positioning the sensor elements in this way improves the detection of urinary wetness which normally occurs toward the front of an absorbent article, detection of faecal wetness which normally occurs to the rear of an article, and detection of wetness resulting from perspiration which can frequently occur, for example, toward the sides in the crotch area near the crease of the wearer's legs, and toward the middle of the diaper.

The sensor may also provide means to detect temperature, pressure, presence of a gas or odour in the absorbent article and/or the presence of a biological or chemical marker indicating presence of bacteria, sugar, parasites or the like in the urine or faeces. This is particularly useful for patients who lack the ability to control where and/or when a voiding event will occur. Data pertaining to these further parameters can also be used, in combination with signals from the conductive elements to further characterise a wetness event, provide a diagnostic indicator, or at least give a carer an early indication that a particular patient is in need of further attention. Other sensor elements may also be incorporated to indicate whether the patient is moving or in a sitting. Lying or standing position.

The sensor signals may be logged regularly, say, every 100 milliseconds or sufficiently frequently to reliably and accurately detect and distinguish an event. Signals received by the processor can reveal data indicating for example (i) detection of wetness and (i) location of the detected wetness. These signals can vary over time, as liquid is absorbed through the diaper and further wetness events occur. By monitoring these signals in time, it is possible for the processor to derive further useful parameters such as volume of exudate in an event and total volume absorbed, using mathematical modelling.

Also, the volume of exudate released can be computed using such factors as the distance between sensor elements detecting the wetness, the rate of transfer of moisture between these elements and the absorption properties of the materials used. These materials may include polymer fibres, natural fibres, gels, textiles, fabrics, papers or a combination of these materials.

The processor may also be programmed with or can interrogate a database of "event signatures" or models characterising certain wetness events and correlate the sensor signals with the event signatures/models to characterise wetness events which are detected. The models may be embodied in any form including mathematical models as described above, graphs or look up tables.

Advantageously, by including laterally placed sensor elements in the sensor pattern, incontinence events can be detected irrespective of whether the patient is in the sitting, lying or standing position. For instance, if the patient is lying on his side, laterally located sensor elements are more likely

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to detect urinary exudate than the frontal elements which would be activated if the patient was standing or sitting.

Lingering wetness may be indicated by failure of the signal to recover to a normal level. A prolonged high sensor signal value may indicate the presence of faecal matter which, unlike urine, may not be drawn into the absorbent layers of the diaper but remains in contact with the sensor elements. Detection of a faecal event should be accompanied by an alert to a carer to change the diaper so as to avoid prolonged wetness and discomfort. A lingering wetness may also be indicative of a full diaper, resulting from inability of the diaper to draw any more urine away from the wearer. This condition should also be communicated to a carer.

The system of the present invention may be utilised with a diaper to be worn by the patient, which diaper has features which enable it to monitor incontinence, particularly urinary incontinence, by, for example, collecting data from the patient wearing the diaper, and transmitting it to a location where such data may be processed. The diaper may also include features which enable samples of, for example, urine, to be withdrawn in situ from such a diaper, for testing.

FIG. 9 shows a diaper 910 which is adapted to be worn by a patient (not shown). Preferably, the diaper 910 is disposable and/or re-usable, and may have an elasticised waistband 912 and elasticised upper thigh bands 914, 916. The diaper 910 is intended to permit the estimation of the volume of urine flowing from the patient in real time. This is effected by the placing of one or more moisture (wetness) sensors 918 at different locations in the diaper 910. The sensors 918 may form part of a radio transmitting and data capturing arrangement (not shown), such as the one described above.

The sensors 918 may be constituted by conductive inks or other means adapted to detect the presence of moisture. The sensors 918, are connected to the aforementioned arrangement, which may be a purpose designed continence management system which captures the data captured by the sensors 918, which data is recorded via e.g. radio transmission or the like to the processor described above. Some of the data may also be transmitted to nursing staff or a nursing station responsible for the management of the incontinence episode in an appropriate manner for the patient or resident in question.

The conductive inks used in the sensors 918 are preferably based on low-cost materials such as carbon, formulated on the carbon content of different concentrations and composition, to achieve the most appropriate sensitivity for moisture detection. Prior art conductive units are silver-based, and accordingly are typically too expensive for use in a disposable diaper.

The choice of carbon or a similar inert substance will reduce the likelihood of interference with chemical markers, which may be incorporated into the sensors 918, for the detection of clinically relevant substances of the type referred to earlier in this specification. Information captured by the chemical markers may be processed for improved management of clinical conditions of residents and patients by medical or nursing staff.

Preferably, the conductive ink will be such that rapid drying or curing will be achieved to enable manufacture of disposable diapers 910 to be carried out at rates consistent with the production of existing and future diapers, presently in the order of 400 diapers per second. The manufacturing process may be carried out using ultraviolet light in a manner similar to that used in rapid curing of dental materials for various dental procedures such as dental fillings.

In a preferred arrangement, the volume of urine passed by the resident or patient, preferably in a unit of time, will be

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established using a mathematical model computed by using such factors as the distance between sensors **918**, the rate of transfer of moisture between sensors **918**, and the absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres.

Turning now to FIG. **10**, a diaper or the like **1020** which may fundamentally be similar to the diaper **910** of FIG. **9**, and which is adapted to be worn by a patient or resident suffering from some form of incontinence. Preferably, the diaper **1020** is disposable and/or re-usable, and preferably has an elasticised waistband **1022** and elasticised upper thigh bands **1024**, **1026**.

The diaper **1020** has a sleeve **1028** located preferably in the area of the diaper **1020** close to the pubic area of the patient or resident. The sleeve **1028** is intended to house a diagnostic strip or the like **1030**. Such diagnostic strips **1030** may be of the Multistix/Combistix type or similar to other strips which are able to detect relevant substances in urine, for example blood, sugar, nitrites, leucocytes, urea, specific gravity, protein, and other substances. As some of the chemical sensors on the strips **1030** use and are derived from blood products, the sleeve **1028** will protect the skin of the wearer from such blood derived products and thus accidental infection with hepatitis B, hepatitis C or HIV.

It is considered that as the information to be obtained from the diagnostic strips **1030** may need to be obtained within certain time frames, the sleeve **1028** will need to allow for a sufficient volume of urine to be captured so that the urine may make contact with the strip **1030**, and for radio transmission of data to take place within the required time frame.

FIGS. **11a** and **11b** show front and rear views of an exemplary sleeve **1128** for a diagnostic strip **1130**. The sleeve **1128** is secured to diaper **920**, **1020** as will be described hereinafter, and is designed and constructed of materials which will attract and capture urine from the patient or resident. This will expose the chemical sensors on the strip **1130** to the collected urine.

The front **1132** of the sleeve **1128** may be provided with a V-shaped notch **1134** for ease of insertion of a diagnostic strip **1130**. Pores and channels **1136** may be provided to facilitate the drawing in of the urine to the interior of the sleeve **1128**, effectively "sucking up" the urine. The rear **1138** of the sleeve **1128** may be provided with adhesive material **1140** for attaching the sleeve **1128** to the diaper **1120** or pad, in much the same manner as used in feminine hygiene products.

A sleeve **1128** will allow urine to be captured in sufficient volume to permit the detection of relevant clinical substances. The interpretation of the results of such detection are preferably based upon a recalibration of what may be regarded as normal or abnormal, compared to existing "dipsticks", which have established normal and abnormal values for interpretation. This re-standardising may be required to take account of any alteration which may occur in the components in the urine samples, as a result of the present invention. For example, diaper fibres may trap some white blood cells, so that a new "normal value" may be needed to be established to cater for such a possibility. As a consequence, a new lower value for the number of leucocytes in a sample may be required.

Another example relates to the test for the albumen:creatinine ratio in a spot urine sample. A level of 0.7 mg/mmol corresponding to a urinary excretion rate of more than 5 mgm/min would indicate a high-risk (in cardiovascular terms) patient requiring aggressive treatment. This marker of arterial damage may be considered with raised cholesterol and hypertension as a serious risk factor for cardiovascular

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disease. Such values would be revised if necessary for the purposes of the present invention.

The sleeve operates as follows. Urine is drawn into the sleeve **1128** via capillary action, osmosis and semipermeable membrane processes, thereby bringing the urine into contact with a diagnostic strip **1130**, which may be a proprietary strip such as marketed under the Bayer and Roche brands, to enable the "reading" to take place in a timely fashion. The carer or nurse will have been alerted to the availability of the urine sample through the radio-based system and software-based system described earlier in this specification.

Patients or residents may be required to take standard known quantities of substances such as creatinine to carry out reliable, accurate tests which the incontinence management system is able to interpret reliably. Such ingested substances may be excreted in an unmetabolised form, for example, as creatinine asparagine, or may be actively metabolised and measured as a metabolite in the urine.

The embodiment of FIGS. **12** and **13** of the present invention makes possible the interpretations of findings in near real time, as the requirement of testing fresh, recently passed, urine is essential for the most accurate interpretations to take place.

In FIG. **12** there is shown a pad **1242** which preferably is adapted to be attached to a diaper (not shown) of a neonate, baby or a child, more preferably by adhesive means such as **1244**. The pad **1242** itself is preferably formed from an absorbent material **1246** such as a sponge or sponge-like material e.g. containing super absorbent particles, to take up urine excreted by the baby. The pad **1242** may also preferably be fitted with a transmitter **1248** for transmitting data to the system(s) described previously in this specification. One example of such a signal would be a signal representative of the fact that voiding had taken place. This may be accomplished by linking the transmitter **1248** with a wetness sensor (not shown).

Currently, there are three existing sample collection methods, where the collection samples are carried out by "catch" techniques, adhesive collection bags, or suprapubic bladder puncture. There are also "time interval" tests, such as 1-hour and 2-hour tests to establish levels of incontinence during the stated time intervals, in which conventional pads are simply weighed to determine the volume of urine. These are termed "pad tests".

The pad **1242** shown in FIG. **12** is much more sophisticated. It preferably comes in three versions. The first version would be a "wetness only" signalling pad, where a parent or nurse would be alerted in real time of passage of urine, would collect the pad and place it in a suitable container to be sent promptly to the microbiology and pathology lab for testing, or would draw up the urine via a syringe for placement in a container, with the container being sent to the lab.

The second type involves the pad **1242** having a collecting chamber (not shown) incorporated therein, into which urine has been drawn. This chamber is preferably removable, so that it may be removed when a predetermined amount of urine, or urine passed in a predetermined period of time has been passed, and sent to the microbial/pathology lab.

The third type of pad **1242** would have a chamber such as that described in relation to the second type, but which would include diagnostic strips of the type and purpose described hereinbefore in relation to FIGS. **9** to **11b**. The design of the collection chamber, sleeve or pocket will be such that it will collect urine for dipstick testing, for collection of samples to be transported for pathology/bacteriology testing, or in situ testing using the new sensors designed for the incontinence management system.

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The collection chamber, sleeve or pocket will be designed in conjunction with the diaper to which it is attached, which diaper draws and feeds the urine into the chamber, to maximise the volume of urine collected, when only small voids have occurred.

Alternatively, urine may be expunged from a urine-soaked pad 1242 via a special container which may expel urine by the use of a plunger (not shown), which may be compared to the plunger in a coffee plunger, which is able to force urine into a sealed compartment (not shown), separate from the pad 1242.

The pad 1242 may have capillary channels (not shown, but preferably similar to channels 1136 of FIG. 11a, to draw the urine towards the collection chamber. The pad 1242 and/or diaper containing the pad 1242 may also preferably use materials designed for osmosis, capillary action or other manner of providing directional flow of urine to assist in the transfer of the urine to a location where it is required. FIG. 13 shows an alternative pad 1350, which may be generally similar to pad 1242 of FIG. 12, but which has a generally cylindrical shape.

Reference is now made to the extension of the present invention to other bodily fluids and exudates from the body of a person. In the case, for example, of serous and other exudates, a dressing for a wound are preferably provided such that information about the wound may be relayed via sensors located on or in association with the dressing, which would otherwise be difficult to determined because conventional dressings or casts would be in the way.

It may also be the intention of the present invention to provide sensors of the dipstick and/or electronic type for dressings on wounds. Additional components, ions and chemical markers of bodily fluids or exudates from the body, may be detected in situ or via the sensors located on or in association with the sensors. Presently, such body products are tested away from the patient in biochemical and bacteriological laboratories. The sensor-equipped dressings may also be used to inform nursing staff of ooze, and content.

It is to be understood that various modifications, additions and/or alterations may be made to the parts previously described without departing from the ambit of the present invention as defined in the claims appended hereto.

The invention claimed is:

1. A moisture monitoring system for monitoring wetness in one or more absorbent articles, the system including:

an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article;

a processor; and

user interface for communicating with a user of the system; wherein the processor executes an algorithm to analyze the one or more sensor signals by applying the one or more received sensor signals to a pre-determined mathematical model to characterize a wetness event in an absorbent article; and

wherein the system has devised the pre-determined mathematical model using sensor signal data previously received by the system, the mathematical model representing a relationship between one or more variables obtainable from the received sensor signals and a characteristic used to characterise a wetness event.

2. A moisture monitoring system according to claim 1 wherein the processor executes the algorithm to characterise a wetness event in an absorbent article by determining one or more of:

(i) an estimated volume of exudate in a wetness event; and (ii) the nature of exudate in a wetness event.

3. A moisture monitoring system according to claim 1 wherein the system uses the received sensor signals and/or

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variables derived from the received sensor signals to derive one or more parameters suitable for use in the mathematical model.

4. A moisture monitoring system according to claim 3 wherein the system applies variables derived from the one or more received sensor signals to optimize the mathematical model for characterizing a wetness event.

5. A moisture monitoring system according to claim 1 wherein the one or more sensor signals are indicative of one or more of:

(i) conductivity of the exudate;
(ii) temperature of the exudate;
(iii) location of the exudate;
(iv) pH of the exudate;
(v) pressure within the absorbent article;
(vi) odour within the absorbent article;
(vii) presence of a gas in the absorbent article;
(viii) presence of blood and/or a biological marker and/or a chemical marker in the exudate.

6. A moisture monitoring system according to claim 1 wherein variables derived from the sensor signals are selected from the group including:

(i) area under a sensor signal curve;
(ii) highest sensor signal value in a predetermined time period;
(iii) maximum value of a leading edge of the sensor signal;
(iv) rate of decay of sensor signal after a leading edge;
(v) a volume estimated in a previous wetness event;
(vi) time of onset of a wetness event;
(vii) time of termination of a wetness event; and
(viii) duration of a wetness event;
(ix) time of day of a wetness event; and
(x) time elapsed since last wetness event.

7. A moisture monitoring system according to claim 1 wherein the processor is configured to determine one or more of:

(a) a likelihood of an imminent wetness event;
(b) an estimate of when a wetness event is likely to occur;
(c) an estimate of a degree of fullness of an absorbent article; and
(d) an estimate of when an absorbent article is likely to reach its absorbent capacity.

8. A moisture monitoring system according to claim 1, wherein the user interface includes a wireless transmitter configured to transmit a signal to a user of the system to indicate that a predetermined volume of wetness has been detected in an absorbent article.

9. A moisture monitoring system according to claim 1 wherein the system is configurable to provide a toileting or voiding diary.

10. A moisture monitoring system according to claim 1 wherein the system is configurable to derive a toileting or voiding schedule for an individual, based on wetness events monitored using the monitoring system.

11. A moisture monitoring system according to claim 10 wherein the system is configured to predict, based on a derived toileting or voiding schedule, when an individual is likely to experience a wetness event which meets pre-defined criteria for manual checking.

12. A moisture monitoring system according to claim 1 wherein the system is further adapted to communicate automatically, an alert to a carer when one or more pre-defined criteria for manual checking are satisfied.

13. A moisture monitoring system according to claim 1 wherein the system is configured to classify a possible form of incontinence suffered by a patient monitored by the system, the form of incontinence being selected from the group

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including urinary, fecal, dribble, stress, overflow, urge, mixed urinary (MUI), total and functional incontinence.

14. A moisture monitoring system according to claim 1 wherein the system is configured to perform one of recognizing and predicting the occurrence of lingering wetness in a region of an absorbent article.

15. A moisture monitoring system according to claim 1 wherein the processor is affixable to a sensor, an absorbent article or to a garment worn by a wearer of an absorbent article.

16. A moisture monitoring system according to claim 1 wherein the processor is incorporated into a central monitoring station adapted to receive sensor signals from a plurality of sensors associated with one or more absorbent articles.

17. A moisture monitoring system according claim 1 wherein the processor includes a pre-processor associated with a sensor of an absorbent article.

18. A moisture monitoring system according to claim 2, adapted to reconfigure the mathematical model for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type, by: for a training period using the particular individual, the different sensor type or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data; and reconfiguring the mathematical model so that there is satisfactory correlation between wetness estimates produced using the sensor signals and the reconfigured mathematical model, and wetness observations from the observation data obtained during the training period.

19. A moisture monitoring system according to claim 18 wherein reconfiguring a mathematical model involves determining one or more new parameters for the mathematical model.

20. A moisture monitoring system according to claim 18 wherein reconfiguring a mathematical model involves application of a linear regression algorithm.

21. A moisture monitoring system according to claim 18 wherein the observation data includes measurements indicating an amount of wetness in the absorbent article and time of measurement.

22. A moisture monitoring system according to claim 18 wherein the observation data includes one or more of: demographic information; and patient information.

23. A moisture monitoring system according to claim 1 further including one or more sensors for use with an absorbent article being monitored for wetness, the sensor including a plurality of sensor elements arranged in a pattern which provides an improved ability to detect wetness.

24. A moisture monitoring system according to claim 23 wherein the sensor elements are arranged in a pattern in which there are more sensor elements in regions having higher propensity for variable moisture or temperature.

25. A moisture monitoring system according to claim 23 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements extend beyond an edge thereof.

26. A moisture monitoring system according to claim 25 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements extend beyond a front edge thereof.

27. A moisture monitoring system according to claim 23 further including, for each absorbent article being monitored, a signal receiver unit and a connector for connecting sensor elements associated with an absorbent article to an associated signal receiver unit.

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28. A moisture monitoring system according to claim 23 further including, for each absorbent article being monitored, a cover layer over the sensor elements, the cover layer extending beyond an edge of the absorbent article and including means for enclosing a signal receiver unit attachable to one or more of the sensor elements.

29. A moisture monitoring system according to claim 23 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements are arranged for connection to a signal receiver unit outside the absorbent article.

30. A moisture monitoring system according to claim 27 wherein the signal receiver unit includes storage means for storing sensor signals collected over a period of time.

31. A moisture monitoring system according to claim 27 wherein the signal receiver unit includes means for receiving data relating to a patient's toileting activities.

32. A moisture monitoring system according to claim 23 wherein the pattern includes sensor elements positioned toward the sides of the absorbent article, near an opening for receiving a leg of the wearer.

33. A moisture monitoring system according claim 23 wherein the pattern includes sensor elements located at two or more depths of the absorbent article.

34. A moisture monitoring system according to claim 23 wherein the sensor includes a sensor substrate, the sensor substrate having one or more channels arranged between adjacent elements of the sensor.

35. A moisture monitoring system according to claim 34 for use with an absorbent article having super absorbent material arranged in the article so as to draw fluid from the one or more channels in the sensor substrate.

36. A moisture monitoring system according to claim 23 wherein the sensor is provided on a flexible substrate affixable, by adhesive or other means, to an absorbent article wearable by a user.

37. A moisture monitoring system according to claim 23 wherein the sensor elements detect wetness at various identifiable locations with respect to the absorbent article, the locations selected from the group including:

- (a) toward the front of the absorbent article;
- (b) toward the rear of the absorbent article;
- (c) toward a side of the absorbent article; and
- (d) substantially centrally of the absorbent article.

38. A moisture monitoring system according to claim 23 wherein the pattern of sensor elements facilitates improved detection of moisture from a user in a range of positions including standing, sitting, lying prone, lying supine and lying on the side.

39. A moisture monitoring system according to claim 23 wherein the sensor elements are arranged to detect spread of moisture from a wetness event in two or more directions.

40. A moisture monitoring system according to claim 23 wherein the sensor pattern includes one or more of: elongate sensor elements; sensor elements arranged in a grid; and an array of sensor element dots.

41. A moisture monitoring system according to claim 23 wherein the sensor includes sensor elements for detecting one or more of electrical conductivity, temperature, pressure, pH, odour, gas and presence of a biological or chemical marker in exudate and location of exudate.

42. A diaper for a person to wear, for use with the moisture monitoring system of claim 1 wherein said diaper includes a sleeve for the insertion of a diagnostic strip.

43. A diaper according to claim 42 characterised in that said sleeve is located on said diaper close to, in use, the pubic area of a wearer.

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44. A diaper according to claim 42, characterised in that said diaper has means designed to direct fluids excreted by said person, to said sleeve.

45. A diaper according to claim 42, characterised in that said sleeve is provided with a V-shaped notch to facilitate the insertion of a diagnostic strip.

46. A diaper according to claim 42, characterised in that said sleeve is attachable to said diaper by adhesive material.

47. A diaper according to claim 44, characterised in that said means designed to direct fluids excreted by said person, to said sleeve, is constituted by pores and/or channels.

48. A diaper according to claim 47, characterised in that said pores and/or channels are located around the periphery of said sleeve.

49. A diaper according to claim 42, characterised in that said sleeve is adapted to retain a predetermined amount of exudate to facilitate contact of said exudate with said strip.

50. A diaper for a person to wear, for use with the moisture monitoring system of claim 1 wherein said diaper is provided with a plurality of sensors at different locations in said diaper.

51. A diaper according to claim 50, characterised in that said sensors are wetness sensors.

52. A diaper according to claim 51, characterised in that said sensors are adapted to permit the estimation of the volume of exudate flowing from the patient in real time.

53. A diaper according to claim 52, characterised in that the volume of exudate passed by the person wearing said diaper, preferably in a unit of time, is established using the mathematical model and computed by using such factors as the distance between said sensors, the rate of transfer of moisture between said sensors, and the absorption properties of the

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materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres.

54. A diaper according to claim 53, characterised in that data from said sensors is transmitted using radio technology, and in that said data is processed using software running the aforementioned mathematical model.

55. A diaper according to claim 50, characterised in that each of said sensors is constituted by conductive inks.

56. A diaper according to claim 50, characterised in that the spacing of said sensors is at different thicknesses in material forming at least a part of said diaper.

57. A pad for use with a diaper, and the moisture monitoring system of claim 1, wherein said pad is associated with transmitting means, for transmitting signals representative of an aspect of fluids absorbed by said pad, to a remote location.

58. A diaper according to claim 57, characterised in that said pad includes a chamber for collection of said fluids.

59. A diaper according to claim 58, characterised in that said chamber is removable.

60. A moisture monitoring system according to claim 1 configurable to adapt a mathematical model to characterise a wetness event in an absorbent article being monitored using one or more of a new sensor type, new sensor element and a new type of absorbent article not previously used with the moisture monitoring system.

61. A moisture monitoring system according to claim 1 wherein the processor is configured to receive automatically data pertaining to known features of an absorbent article selected from a group including: volume capacity, type, brand and location of sensors embedded therein.

* * * * *



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Mail Stop PATENT APPLICATION
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Sir:

Transmitted herewith for filing is a CONTINUATION-IN-PART application of pending PCT/AU2005/001667 which has designated the U.S., filed on 28 October 2005 of

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for **INCONTINENCE MANAGEMENT SYSTEM AND DIAPER** and which is hereby incorporated by reference. The application comprises a 46-page specification, including 79 claims (8 independent) and Abstract and 11 sheets of drawings.

Accompanying the application for filing is:

Preliminary Amendment

A certified copy of **Australian** Provisional Application No. **2006902251** filed **2 May 2006**, and **Australian** Application No. **2004906315** filed **3 November 2004**, will be filed in due course, the priority of which is claimed under 35 U.S.C. §119 and which is hereby incorporated by reference.

This application is being filed under 37 C.F.R. §1.53(f) (without Declaration or Filing Fee). The required Declaration and Filing Fee will be filed subsequently. A duplicate copy of this sheet is enclosed.

Should a fee be necessary to obtain a filing date, e.g. paying the basic fee for nationalizing a PCT application, the Commissioner is hereby authorized to charge payment of any fees set forth in §§1.16, 1.17 or 1.492 during the pendency of this application, or credit any overpayment, to Deposit Account No. 06-1358. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
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INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

Field of the Invention

- 5 The present invention relates to moisture monitoring. It relates particularly but not exclusively to systems, devices and methods for monitoring moisture in absorbent articles such as diapers, incontinence garments, dressings and pads, resulting from wetness events caused by, for example, urinary and/or faecal incontinence. It also relates to a diaper for use with such a system.

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Background to the Invention

- Incontinence is a condition in which there is uncontrolled release of natural discharges or evacuations. While some forms of incontinence are more widespread, the condition usually affects women, the elderly and the infirm.
- 15 Urinary incontinence refers to loss of bladder control resulting in involuntary or uncontrolled urination. Other forms of incontinence including faecal or bowel incontinence also exist. In the context of the present application, the term "incontinence" is to be taken to include urinary and faecal incontinence.
- 20 Incontinence, in the context of this specification, includes urinary and faecal incontinence, and management of such incontinence is to be seen in the context of persons located in hospitals, nursing homes, aged care facilities, geriatric institutions, private homes and the like.
- The aforementioned incontinence, when unchecked, may result in the person
- 25 suffering from the condition experiencing discomfort or at least embarrassment, and in the existence of unpleasant odours and environment for others in the vicinity of the person. In addition, health regulations or protocols may prescribe a maximum period, such as 15 minutes, for which a patient may be left in a wet state caused by incontinence. In the past, to comply with such requirements, it
- 30 has been necessary for nursing staff to manually check each patient at least once during the prescribed period. Apart from the unpleasantness experienced by nursing staff in carrying out such manual checks, such a regimen may place

a severe strain on staff resources, and may constitute an interruption to patients' rest and sleep.

5 A range of different incontinence types are recognised. Stress incontinence refers to involuntary loss of urine immediately associated with coughing, sneezing, lifting, straining or other physical exertion. The term "stress" relates to the mechanical stress of the abdominal muscles compressing the bladder wall, working against weakened sphincter muscles. Childbirth, obesity, constipation and changes in the sphincter muscles after the menopause can aggravate
10 stress incontinence as can the use of some drugs.

Urge incontinence refers to the involuntary loss of urine coupled with a strong desire to urinate. Often the sufferer is unable to reach the toilet before there has been a urine loss. The need to visit the toilet may occur very frequently during
15 the day and often at night also. Urge incontinence is generally caused by an overactive or "unstable" bladder which contracts involuntarily in an attempt to empty. The contractions give rise to an urgent desire to pass urine and uncontrolled leakage occurs before a toilet is reached. Mixed Urinary Incontinence (MUI) refers to involuntary leakage associated with urge
20 incontinence and also with exertion, effort, sneezing, or coughing associated with stress incontinence.

Overflow incontinence refers to involuntary loss of urine associated with a chronically distended and overfull bladder. The bladder may be distended as a
25 result of incomplete emptying which may be caused by obstruction to the outlet of the bladder or as a result of a failure of the bladder muscle to contract properly. Bladder failure of this kind may be caused by disease of the nervous system, by some drugs or by psychological factors.

30 Dribble incontinence refers to leakage of urine without warning or provocation. This is a demoralising condition because leakage can occur at anytime and is unpredictable. Persons suffering from dribble incontinence often need to wear protective pads or diapers throughout the day and night. Total incontinence is a term sometimes used to describe continuous leaking of urine, day and night, or

periodic large volumes of urine and uncontrollable leaking. Some people have this type of incontinence because they were born with an anatomical defect. It can also be caused by a spinal cord injury or by injury to the urinary system from surgery.

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Functional incontinence occurs where the ability to get to the toilet is impaired either by physical conditions such as paralysis or arthritis, or mental impairment. This is very common in nursing home patients who rely on assistance from others for mobility.

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Although incontinence is relatively widespread, it is a condition which must be treated with sensitivity as it can be uncomfortable and embarrassing for sufferers and carers alike. When left unchecked, incontinence can become more embarrassing due to the existence of unpleasant odours associated with incontinence events and this can create an unpleasant environment for others in the vicinity of the incontinence sufferer. In addition, exudate escaping the body as the result of an incontinence event often contains bacteria, so unchecked wetness can create health and hygiene problems. Also, health regulations or protocols may prescribe a maximum period, for example 15 minutes, for which a patient suffering incontinence may be left in a wet state.

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In the past, to comply with regulations and protocols and to ensure that patients in care institutions such as hospitals, nursing homes, aged care facilities and geriatric institutions are well looked after, it has been necessary for staff to manually check patients suffering from incontinence on a regular basis. Apart from the unpleasantness involved with manual checks, such a regimen also places a strain on staff resources. Often manually checking for wetness will also cause interruption to a patient's rest and sleep.

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Incontinence indicators and detection systems exist. However, they have done little to improve the current situation in which carers must manually and regularly check patients for wetness. Existing incontinence detection systems are generally unable to distinguish a urinary incontinence event from a fecal incontinence event or the size of these events. Existing systems are also

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deficient in that they alarm or alert a carer simply when wetness is detected, with no indication of the degree of wetness present. This can cause more time wasted than saved as very small volumes e.g. of urine or perspiration may trigger an alert even though the patient does not actually require attention from a carer. This can also be a source of embarrassment for the patient.

Some systems involve complicated circuitry and are expensive and difficult to manufacture. Since most diapers and pads are disposable both for efficiency of use and hygiene reasons, complicated sensor systems do not lend themselves to widespread uptake and ongoing use.

Some systems are clumsy to use and the sensors can interfere with the absorbent capacity of the diaper or pad with which they are used. Others again are generally incompatible with current care practices and actually create additional work, significant complications or changes in care practices undermining any benefits they may offer and making them less susceptible to widespread uptake and ongoing use.

The present invention aims to improve upon these systems, to improve efficiency in monitoring and management of continence with minimal changes in care practices, or at least provide a useful alternative to existing systems.

Summary of the Invention

According to a first aspect of the present invention, there is provided a moisture monitoring system for monitoring wetness in one or more absorbent articles. The system includes an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article, a processor for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article and a user interface for communicating with a user of the system.

The processor may execute an algorithm to devise automatically a mathematical model for characterising a wetness event in an absorbent article. Alternatively, the processor executes an algorithm to perform the analysis,

where the algorithm applies the sensor signals to a pre-determined mathematical model to characterise a wetness event in an absorbent article by determining e.g. an estimated volume of exudate in a wetness event and/or the nature of exudate in a wetness event. Alternatively the algorithm may apply variables derived from the one or more sensor signals to the mathematical model.

The processor may apply sensor signals and/or derive variables from the sensor signals for use by the algorithm to determine one or more parameters suitable for use in a mathematical model for characterising a wetness event. The sensor signals may indicate one or more of conductivity of the exudate, temperature of the exudate, location of the exudate, pH of the exudate, pressure within the absorbent article, odour within the absorbent article, presence of a gas in the absorbent article and presence of blood and/or a biological marker and/or a or chemical marker in the exudate.

Variables derived from the sensor signals may be selected from the group including but not limited to area under a sensor signal curve, highest sensor signal value in a predetermined time period, maximum value of a leading edge of the sensor signal, rate of decay of sensor signal after a leading edge, a volume estimated in a previous wetness event, time of onset of a wetness event, time of termination of a wetness event, duration of a wetness event, time of day of a wetness event and time elapsed since last wetness event.

The processor is configured to determine a range of predictions based on patterns identified from sensor signals and/or using mathematical models. These predictions may include a likelihood of an imminent wetness event, an estimate of when a wetness event is likely to occur, an estimate of a degree of fullness of an absorbent article and/or an estimate of when an absorbent article is likely to reach its absorbent capacity.

Preferably, the user interface includes a wireless transmitter configured to transmit a signal to a user of the system to indicate that a predetermined volume of wetness has been detected in an absorbent article. The processor

may also be configured to provide a toileting or voiding diary and/or to derive a toileting or voiding schedule for an individual, based on wetness events monitored using the monitoring system, preferably over a number of days.

- 5 The system may predict, based on a derived toileting or voiding schedule, when an individual is likely to experience a wetness event which meets pre-defined criteria for manual checking. Further, the system may be adapted to communicate automatically, an alert to a carer when one or more pre-defined criteria for manual checking are satisfied.

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In one embodiment, the processor is configured to classify a possible form of incontinence suffered by a patient monitored by the system, such as urinary, fecal, dribble, stress, overflow, urge, mixed urinary (MUI), total and functional incontinence. The processor may also recognise and/or predict lingering

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wetness in a region of an absorbent article.

The processor may be affixable to a sensor, an absorbent article or to a garment worn by a wearer of an absorbent article. Alternatively, the processor can be incorporated into a central monitoring station adapted to receive sensor
20 signals from a plurality of sensors associated with one or more absorbent articles. A pre-processor may also be associated with a sensor of an absorbent article, locally to the article.

- 25 Preferably, the processor is adapted to execute an algorithm to reconfigure one or more mathematical models for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type. This may be achieved by, for a training period using the particular individual, the different sensor type or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data,
30 and reconfiguring the mathematical model so that there is satisfactory correlation between the estimates produced using the sensor signals and the reconfigured mathematical model, and the observation data obtained during the training period. Reconfiguring a mathematical model preferably involves

employing an algorithm to determine one or more new parameters for the mathematical model e.g. using a linear regression technique.

5 Observation data includes measurements indicating an amount of wetness in the absorbent article and time of measurement. It may also include demographic information about the patient such as age and gender and patient information such as food and fluid intake and medication regimes.

10 According to another aspect of the present invention, there is provided a sensor for use with an absorbent article being monitored for wetness. The sensor includes a plurality of sensor elements arranged in a pattern which provides an improved ability to detect wetness. The pattern may involve more sensor elements in regions having higher propensity for variable moisture or temperature, within the absorbent article. The pattern may include sensor elements positioned toward the sides of the absorbent article, near an opening for receiving a leg of the wearer. The pattern may also include sensor elements located at two or more depths of the absorbent article. The sensor pattern includes one or more of elongate sensor elements, sensor elements arranged in a grid and an array of sensor element dots.

20 In one embodiment, one or more sensor elements extend beyond an edge of the absorbent article, preferably a front edge, and includes a connector for connecting the sensor elements to a signal receiver unit easily without significant disturbance to the patient being monitored.

25 A cover layer may be provided over the sensor elements which also extends beyond an edge of the absorbent article and includes means such as a pouch, pocket or flap for enclosing a signal receiver unit attachable to one or more of the sensor elements. It is preferable that one or more sensor elements are arranged for connection to a signal receiver unit outside the absorbent article.

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The signal receiver unit may include storage means for storing sensor signals collected over a period of time. Alternatively or additionally, the signal receiver unit may include means for receiving data relating to a patient's toileting

activities e.g. by way of buttons on the device, cable input or contactless communication. The signal receiver unit may also include a transmitter for transmitting sensor signals or variables derived therefrom to a remotely located device.

5

In one embodiment, the sensor includes a sensor substrate having one or more channels arranged between adjacent sensor elements. Such a sensor is suitable for use with an absorbent article having super absorbent material arranged correspondingly in the article, so as to draw fluid from the one or more
10 channels in the sensor substrate. Preferably, the sensor is provided on a flexible substrate affixable, by adhesive or other means, to an absorbent article wearable by a user.

The sensor elements detect wetness at various identifiable locations with
15 respect to the absorbent article including toward the front of the absorbent article, toward the rear of the absorbent article, toward a side of the absorbent article, and substantially centrally of the absorbent article. Desirably, the pattern of sensor elements facilitates improved detection of moisture from a user in a range of positions including standing, sitting, lying prone, lying supine and lying
20 on the side. Preferably, the sensor elements are also arranged to detect spread of moisture from a wetness event in two or more directions. The sensor may include sensor elements for detecting one or more of electrical conductivity, temperature, pressure, pH, odour, gas and presence of a biological or chemical marker in exudate and location of exudate.

25

According to another aspect of the present invention, there is provided a method for monitoring moisture in an absorbent article including the steps of receiving one or more sensor signals associated with the absorbent article, the sensor signals indicating wetness in the absorbent article, applying one or more
30 sensor signals to a predetermined mathematical model for characterising a wetness event and, based on the mathematical model, characterising a wetness event in the absorbent article. A method for devising the mathematical model is also disclosed.

Characterising a wetness event preferably involves ascertaining one or more of an estimated volume of exudate in a wetness event and the nature of the exudate although it may also involve determining whether predefined criteria, defined by a mathematical model, have been met. A user may be notified
5 automatically if one or more predetermined notification criteria are met.

Preferably, the algorithm executing the predetermined mathematical model receives as inputs one or more variables derived from the one or more sensor signals and these variables may be derived automatically using a processor as
10 described above. The method may also include maintaining a toileting or voiding diary, being a log of monitored wetness events, also referred to as a bladder chart. A toileting or voiding schedule may also be derived for an individual being monitored, based on wetness events monitored using the monitoring system.

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The method may also include predicting, based on a derived toileting or voiding schedule, when an individual is likely experience a wetness event which meets pre-defined criteria for manual checking and this can streamline patient care. The method also facilitates reconfiguring of one or more mathematical models
20 for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type by, for a training period using the particular individual, the different sensor type and/or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data and reconfiguring the mathematical model so
25 that there is satisfactory correlation between the estimates produced using the sensor signals and the reconfigured mathematical model, and the observation data obtained during the training period. Reconfiguring a mathematical model may involve determining new parameters for the mathematical model e.g. by application of a linear regression algorithm.

30

Another aspect of the present invention provides a diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper includes a sleeve for the insertion of a diagnostic strip.

In another aspect of the present invention, there is provided a diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper is provided with a plurality of sensors at different locations in said
5 diaper.

In yet another embodiment of the invention, there is provided an incontinence management system or a system for the management of other exudates from the body of a person, characterised by an article adapted to be worn by the person, sensing means associated with said article and adapted to sense a
10 condition, and transmitting means adapted to transmit a signal generated by said sensing means to a location.

Brief description of the drawings

15 The present invention will now be described in greater detail with reference to the accompanying drawings. It is to be understood that the particularity of the accompanying drawings does not supersede the generality of the preceding description of the invention.

Figure 1 is a schematic diagram illustrating features of a moisture
20 monitoring system according to an embodiment of the present invention.

Figure 2 is a flow diagram showing typical steps in using the monitoring system for continuous monitoring of patients for wetness, using a sensor.

Figure 3 is a flow diagram showing steps involving use of the invention for care planning.

25 Figure 4 is a flow diagram indicating the steps involved with calculating or re-calculating parameters of a mathematical model.

Figures 5a and 5b illustrate an example of a sensor used with an absorbent article, according to an embodiment of the present invention.

Figure 6 represents a sensor signal showing temperature versus time.

30 Figure 7 illustrates an embodiment of a sensor having a channel between adjacent sensor elements.

Figure 8 is a schematic illustration of a diaper or adult incontinence garment showing a pattern of sensor elements according to an embodiment of the invention.

Figure 9 is a diagrammatic perspective view of a diaper in accordance
5 with one embodiment of the present invention.

Figure 10 is a diagrammatic perspective view of a diaper in accordance with a second embodiment of the present invention.

Figure 11a is a front elevation of an embodiment of a sleeve for a diagnostic strip. Figure 11b is a rear elevation of an embodiment of a sleeve for a diagnostic strip.

Figure 12 is a diagrammatic perspective view of a pad for use in a diaper.

Figure 13 is a diagrammatic perspective view of an alternative pad for use in a diaper.

10 Detailed Description

In one aspect, the present invention provides a system for monitoring wetness in one or more absorbent articles such as pads, diapers, adult incontinence garments or the like. Throughout this description, reference will be made to a range of absorbent articles. It is to be understood that the list of absorbent
15 articles identified above is not an exhaustive list and that other absorbent articles and garments are within the scope of the present invention. It is also to be understood that a reference in this specification to any one such article, such as a "diaper" is to be taken to be a reference to any and all other suitable absorbent articles including incontinence garments, pads and the like.

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The moisture monitoring system of the invention is generally intended for use in facilities in which staff are required to monitor and care for individuals who suffer from various incontinence conditions. These facilities include hospitals, nursing homes, aged care facilities, geriatric institutions, private homes, respite
25 centres and the like, although it may also be used in other environments e.g. with infants. The system provides useful information to assist users, e.g. carers in the provision of more efficient care to sufferers of incontinence and the like.

As well as the urinary and faecal incontinence and wetness events referred to above, the present invention also has applicability in the detection, monitoring and management of conditions in which other fluids and exudates from the body may be present, including wound management. Thus, as well as the urinary and faecal incontinence, the present invention may be utilised in the management, monitoring and treatment of the production of other bodily fluids and exudates from the body of a patient or resident such as cerebro-spinal fluid (CSF), peritoneal fluid, synovial fluid from joints and bursae around joints, and material discharged from wounds.

Referring now to Figure 1 there is shown a schematic diagram illustrating features of a moisture monitoring system. The system includes input 104 which receives sensor signals, processor 106 and user interface 108. The system may be used with a plurality of sensors 102 each of which may be associated with a different individual being monitored. The sensor signals received by the input indicate whether moisture is present in an absorbent article being monitored. This may be achieved using a range of different sensor types and arrangements.

In one embodiment, presence of moisture is indicated by an increase in conductivity between spaced electrodes as a result of moisture forming a conductive bridge between them. These sensors could be replaced by or complemented with e.g. thermistor elements in which a change in temperature is indicative of the presence (or absence) of moisture. Conductivity and temperature signals will change with time, as moisture is drawn away from the skin's surface and into the absorbent article.

Alternatively or additionally, the sensor may include sensor elements monitoring other variables which change in the presence or absence of moisture (exudate), or when the volume of exudate changes. These sensor elements may include elements detecting changes in pH, pressure, odour and the presence of gas, blood, a chemical marker or a biological marker in the exudate, or any

combination of these. The sensor elements may also be arranged in such a way that they convey to the processor the location of moisture detected.

5 An extensive list of clinically relevant medical conditions may be recognised or suspected by the detection of a number of metabolites, chemicals and ions, as well as other substances and cells of different types, in urine. Such materials as nitrites, amino acids, Beta-2 microglobulin, such measurements as pH, osmolality, white cell count, protein, specific gravity, and such conditions as multiple myeloma and haematuria, may be detected by testing urine from a
10 patient e.g. using a sensor according to an embodiment of the invention.

Processor 106 executes an algorithm to perform an analysis of the sensor signals to characterise wetness events occurring in the absorbent articles being monitored. In one embodiment, the analysis involves modelling a relationship
15 between a dependent variable such as volume of exudate in a wetness event, and sensor signals that can be used to estimate the volume. In one embodiment, the processor executes an algorithm to perform the analysis. Preferably, the algorithm applies variables derived from the sensor signals to the mathematical model to characterise a wetness event.

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The algorithm may be programmed in software or in hardware using a range of different techniques and languages known to a person skilled in the relevant art. Advantageously, the algorithm enables the processor to combine different types of data which can be obtained from the sensor signals, and analyse that data to
25 characterise a wetness event, thereby providing more useful information to a user of the system. Moreover, the algorithm enables the system to adapt to new sensor types and new types of absorbent article which have not been used with the moisture monitoring system before.

30 The processor may be configured to receive data (either entered manually or automatically by, for example, scanning a barcode on a diaper) pertaining to known features of a diaper or incontinence garment being worn by a patient. The features may include the volume, type or brand of the diaper/garment, and the location of the sensors embedded therein. This data enables the processor

to identify the type of pad and devise or apply a suitable mathematical model which when used in combination with the data received from the sensor(s) can enable the processor to perform powerful analysis. Because the processor uses wetness and e.g. location data sampled over successive periods; and
 5 algorithms using mathematical models to characterise wetness events, it is also able to characterise phantom events or noise, which may result from the patient moving or from intermittent brief interference from other components in the system, and disregard these artefact points.

10 To characterise the volume of an event, the algorithm applies one or more variables derived from the sensor signals of an individual's absorbent article to a mathematical model which estimates the volume of liquid in the event. The variables derived from the sensor signals may include one or more of: area under a sensor signal curve (e.g. signal magnitude versus time); highest sensor
 15 signal value in a predetermined time period; maximum value of a leading edge of the sensor signal; the rate of decay of sensor signal after a leading edge; volume estimated in a previous event; time of onset; time of termination of an event; duration; time of day; and time elapsed since the last detected wetness event; although it is to be understood that this list is not exhaustive.

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In addition to volume (or instead of), the algorithm may be adapted to characterise other aspects of wetness events such as the nature of the exudate (i.e. urinary or fecal) and whether a series of wetness events can be classified into a particular type of incontinence such as stress, urge, fecal, overflow, mixed
 25 urinary (MUI), dribble, functional and total incontinence. This can be achieved by applying a suitable mathematical model developed by the same means as the models used to characterise different voiding volumes.

Referring now to Figure 4, there is shown a flow diagram indicating steps
 30 involved in an algorithm calculating and/or recalculating parameters of a mathematical model to characterise wetness events with maximum accuracy and/or to optimise its performance.

For a training period, e.g. 3 days, a patient is monitored for wetness. This may involve continually monitoring sensor signals for indications of wetness and upon every variation in sensor values, obtaining observation data by changing the pad, examining the pad and weighing the pad. Additional observation data
5 may be collected such as amount and time of fluid and food intake, as these variables influence the patient's continence function and are therefore potentially influential variables in the mathematical model.

In a step 402, the collected sensor signals and observation data are received by
10 the processor. In a step 404, the processor executes an algorithm performing a regression analysis to formulate parameters for the mathematical model. In a step 406, these parameters are fed back into the mathematical model and a confidence level is determined which indicates how accurately the mathematical model estimates the actual events defined by the observation data. If the
15 confidence level is acceptable (e.g. above $R^2 - 0.6$) then the parameters are accepted and the model updated. If the confidence level is too low, a further regression analysis is performed and the confidence level checked again. The algorithm repeats the regression analysis process until an acceptable confidence level is reached.

20 The same method may be applied to re-calculate parameters of the model. Calculating and recalculating the parameters of the mathematical model utilised by the system is useful for a number of reasons. Firstly, it enables the establishment of an initial mathematical model for predicting particular types of
25 events. Secondly, it allows the system to continually improve the accuracy with which it predicts a patient's continence function and therefore, the efficiency with which care practices can be implemented. Thirdly, by reconfiguring the mathematical model, the system can be adapted to work with different absorbent pads having different absorbent characteristics. In this way, the
30 algorithm can "learn" the characteristics of the pad.

Similarly, the system can adapt to use with additional and/or different sensor types. Again, the ability of the system to "learn" the behaviour of different sensors and sensor elements makes the system adaptable to new products and

technologies which will improve accuracy and sensitivity, without the need for a major overhaul of the software employed by the processor. Alternatively/additionally, the processor may re-define one or more mathematical models to suit new sensors, sensor elements or absorbent articles. The need to re-define a mathematical model can be minimised by use of relatively generic code, although this can result in slower calculations.

The moisture monitoring system of the present invention can be used to monitor incontinence sufferers more efficiently than existing systems. Figure 2 is a flow diagram illustrating typical steps involved in using the monitoring system for continuous monitoring of patients for wetness using sensors. In a step 202, the system monitors sensors applied to absorbent articles worn by patients in a care institution. If a sensor signal value exceeds an initial trigger value, in a step 204 the processor 106 (Fig 1) derives variables from received sensor signals which, in a step 206 are used as inputs to an algorithm utilising a pre-determined mathematical model to estimate a volume of exudate in a wetness event. The mathematical model may be determined using any suitable statistical modelling technique such as regression analysis. In this example, the algorithm applies a mathematical model to estimate volume of exudate using the equation:

$$Volume - 0.3x(Profile_Area) + 2.4x(Patient_Weight) - 0.6x(Patient_Age) \quad (Eq\ 1)$$

Profile_Area is the area under a curve of sensor signal versus time for a sensor element monitoring exudate conductivity. Eq 1 gives a confidence factor (R^2) of 0.63. It is to be understood, however, that Eq 1 is just one example of a mathematical model which may be used to characterise wetness events and that other models may be derived with also exhibit a satisfactory level of confidence.

In a step 208 the processor executes an algorithm to compare the estimated volume with a pre-defined threshold level. If the estimated volume is less than the threshold, the processor continues to monitor the sensor signals. If the estimated volume exceeds the threshold amount, then in a step 210 the

processor sends an alert to a carer. Once a carer is alerted, the carer attends to the resident and may choose to change the absorbent article and in a step 212, the processor detects that the sensor has been disconnected from the system and resets the sensor data.

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The threshold volume used by the processor to alert a carer may be a "qualifying amount" e.g. indicated as small, medium or large or a quantifying amount being a pre-defined volume e.g. 50ml.

10 Preferably, the processor may also execute an algorithm to compare the estimated volume with a known estimated capacity of the diaper to give carers an indication of when the diaper is likely to become saturated with exudate so that it can be changed before a saturating wetness event occurs and the patient is made to feel uncomfortable by excess wetness.

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The processor may also monitor the total amount of accumulated moisture in a series of wetness events in a single absorbent article and provide an indication to a carer as to when the absorbent capacity of the garment has been or is likely to be reached, to prompt the carer to change the garment for the patient's
20 comfort and wellbeing.

Users may enter data, including patient specific demographic data such as gender, age, height and weight via user interface 108. As indicated in Equation 1 above, these data can also be utilised by the algorithm to estimate e.g.
25 volume. Other entered data may include medical data, i.e. medication, amount of fluid and food intake, details of known conditions, recent surgeries, years in assisted care, years wearing an incontinence garment, continence function if known, and mental condition.

30 The processor 106 may be incorporated into a central monitoring station such as a nurse's station. The processor may also integrate with or be incorporated into existing nurse call and remote patient monitoring systems controlled at the nurse's station. The processor may also be integrated with other care management systems for streamlining access to non-sensor related data

contained within other care management systems such as, for example, fluid and food intake, patient relocation, showering, toileting, surgeries etc.

User interface 108 may also include a transmitter which sends alerts to communication devices such as pagers or nurse phones carried by carers to indicate that there has been a wetness event, or that one is due to occur, or that physical inspection of the patient is required or due. In addition to the detection of wetness events which are estimated to exceed a threshold amount, these conditions warranting physical inspection may include when exudate is fecal in nature or when sensors detect blood, a parasite or a biological or chemical marker in the urine or faeces.

Figure 3 illustrates another use of the invention, where the moisture monitoring system is used in care planning to evaluate and plan the regularity and timing of a carer's manual checking of an individual's continence, and to schedule toileting. The care plan is based on an assessment performed using the monitoring system.

In a step 302, a sensor is allocated to a patient. The sensor has a transmitter unit attached and in a step 304 the patient is monitored for wetness for a continuous period of, for example, 3 to 5 days. During that period, the patient participates in usual activities and the patient is physically checked for wetness by a carer regularly, e.g. every hour. When a sensor signal received by the processor indicates a presence of exudate, an alert is sent to a carer who attends to the patient, changing the pad. Each time the carer checks or attends to the patient, observation data is recorded which includes the nature and amount of exudate (e.g. volume or mass obtained by weighing a soiled pad) and the time of observation.

In a step 306, observation data is used, along with a log of the sensor signals received at the input, to identify patterns in the patient's continence activity. In a step 308 the processor derives automatically, using an algorithm employing another mathematical model, a continence care plan based on the pattern, i.e. frequency and repetition of monitored events. The care plan includes a voiding

or toileting schedule which statistically predicts wetness events based on the observed pattern. This is used by carers to plan the regularity (e.g. times of day) that a patient is to be manually checked for wetness and/or assisted with toileting and to plan when to empty the bladder or bowel, prior to periods in which a patient is known to have a pattern of incontinence events. Normal care of the patient can then take place without the need to continually monitor using a sensor.

The voiding schedule anticipates when a wetness event is statistically likely to occur and this can be used to automatically generate an audible and/or visible alert for a carer (e.g. presented on a screen of the user interface 108 or transmitted to a pager or the like) to attend to the patient by assisting with manual toileting or to change the patient's incontinence garment.

It is recommended that the toileting/voiding schedule is re-evaluated periodically (step 310) to maintain its accuracy, in keeping with changes in the patient's continence patterns. Re-evaluation may take place for example every 3, 6 or 12 months, or whenever actual wetness events do not correspond well with those anticipated by the voiding schedule.

In another use of the invention, the moisture monitoring system includes a log for recording wetness events detected by sensors including the volume, time and nature (urinary and/or fecal) of each event. These data are used to produce a bladder diary. These data may also be combined with details entered e.g. at the user interface 108 which relate to food and fluid intake (amount, kind and time), toileting and also any particular activities that the patient has undertaken.

The log may manifest in a memory device in communication or integrated with the processor. The processor may be located centrally and receive sensor signals relating indicative of wetness of a number of absorbent articles worn by different patients. Alternatively, there may be a pre-processor executing the algorithm located near the sensor, on the absorbent article. That is, the sensor and the part of the processor performing the analysis may be provided together with the sensor. In such arrangement, the pre-processor may also

incorporate a transmitter for transmitting data from the pre-processor to e.g. a central monitoring system which may include a display.

Referring now to Figures 5a and 5b, there is shown a schematic diagram of a sensor 502 according to an embodiment of the invention, applied to an absorbent article 500. The sensor 502 has a sensor element (shown in broken lines) which exhibits a change in conductivity when moisture is present, although other variables such as temperature could be used to detect moisture, as indicated in Figure 6.

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Figure 6 is a graph of temperature versus time. The rise in temperature at point A is indicative of a wetness event and the rate of decline indicates that the temperate moisture is being drawn away from the sensor element, into the absorbent article. The second leading edge peaking at point B indicates the occurrence of a second wetness event and the signal is sustained. This is typically indicative of a situation in which the absorbent article must be changed e.g. because of the size of the wetness event, because the article has reached its absorbent capacity, or a fecal event has occurred in which the exudate cannot be drawn into the absorbent layers of the article.

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Returning to Figures 5a and 5b, an embodiment of the invention is shown in which the sensor elements 502 extend beyond a front edge of the absorbent article 500. In this arrangement, a connector 504 is also provided to which a signal receiver unit 506 may be attached. The signal receiver unit may consist of a storage component which records the time and magnitude of sensor signals. Alternatively/additionally, it may include a transmitter which conveys the time and magnitude of sensor signals to a remotely located processor. Alternatively/additionally, the signal receiver unit may include a pre-processor for executing an algorithm performing analysis of the sensor signals which are then stored locally for downloading and/or transmitted to a remote processor which conveys alerts to carers, formulates bladder diaries, voiding schedules or the like. In such arrangement, the signal receiver unit (i.e. pre-processor) may also include means for receiving data relating to a patient's toileting activities. The data may be received wirelessly via a contactless communication device,

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by a cable connection to an input device or other suitable means for example buttons or the like on the signal receiver unit itself, worn by the patient.

Preferably, signal receiver units 506 are re-useable, and are releasably
5 connectable to the sensors via connectors 504. This connection may utilise any suitable connection means such as a male-female dual-in-line (DIL) connector or the like, as would be known to a person skilled in the relevant art. The signal receiver units may be attached to an absorbent article or to clothing worn by a patient in a manner which is comfortable for the patient to wear, and is also
10 sufficiently robust to minimise the risk of damage or removal while in use. When the diaper/incontinence garment is changed, the signal receiver unit may be disconnected from the soiled sensor, cleaned and attached to a sensor on a new diaper/incontinence garment.

15 Alternatively, the signal receiver units and sensors may be disposable and incorporated into a diaper or absorbent article during manufacture. In this arrangement, the signal receiver unit may not be visible so the sensor may be activated by a switch or button which is felt through the layers of the diaper. Alternatively, a radio-frequency or other contactless system may be used to
20 activate the device and/or transmit sensor signals to a central monitoring station. In a further alternative embodiment, all parts of the monitoring system are re-useable, although this may create hygiene problems and be undesirable for individuals left with the task of cleaning the components.

25 In the embodiments illustrated in Figures 5a and 5b, a cover layer 508 is provided over the sensor elements. In regions of the cover layer affected by exudate, it is preferred that the cover layer material is liquid permeable so that any moisture resulting from a wetness event can be drawn into the absorbent layers of garment 500. In a preferred embodiment, a flap or pouch is provided to
30 contain the signal receiver unit (which may also provide a transmitting/pre-processing/memory functions). The flap or pouch may be provided by a portion 508a of the cover layer which extends beyond and folds over the front edge of the absorbent article and can be fastened in place by adhesive, Velcro® or other means. The flap or pouch deters individuals, particularly those with forms

of dementia or mental illness from tampering with the unit. Preferably, the sensor and absorbent article are arranged in such a way that the signal receiver unit is attachable thereto outside the absorbent article.

- 5 The sensor and other components which are located on the diaper (e.g. transmitter, pre-processor) may be powered by a small battery or electronic component storing energy. Alternatively, the sensor may include or be part of an RFID or other passive device. To conserve power, the transmitter/pre-processor may deactivate when there has been no wetness event for a
10 predetermined length of time. The devices may be reactivated when a wetness event occurs.

The processor analyses signals received from the sensors to characterise wetness events which are detected for each patient. Characterisation of
15 wetness events by the processor may include characterising the cause of a wetness event by making a distinction between wetness resulting from incontinence, perspiration or other leakage or discharge which may occur due to bedsores or decubitous ulcers which can develop in immobile patients.

- 20 A sensor 102 may be incorporated into a pad, diaper or adult incontinence garment when manufactured, or it may be provided separately and attached to an "off the shelf" diaper by way of adhesive or other fixation means. For the latter, sensor elements are provided on a substrate which may be liquid permeable so that exudate released by the wearer passes through the
25 substrate (activating the sensor elements) and is drawn away from the user into the absorbent layers of the diaper. One or more pores and/or channels may be provided in the sensor substrate to facilitate drawing of exudate away from the skin surface into the diaper. Figure 7 illustrates one such embodiment, where there is an elongate channel 702 provided between two elongate sensing
30 elements 704 on a substrate 706 of a sensor. It may be desirable to use a sensor having a substrate of this kind with an absorbent article with super absorbent material correspondingly arranged in the article so as to draw fluid from the one or more channels in the sensor substrate into the absorbent layers and away from the wearer.

In one embodiment, sensors 102 are conductive elements. When an electrolyte such as urine contacts the conductive elements in sufficient quantity, a conductive bridge is formed between the elements and this can be detected by monitoring one or more electrical characteristics of the elements such as resistance or conductance, capacitance or the like. The conductive elements may be formed using any suitable conductive materials or combinations of materials including gold, copper, silver, conductive inks, polymers, tapes, resins and threads, other suitable conductive polymeric materials, conductive film, fibres or electrodes including, for example, an inert metal. Alternatively/ additionally, the sensor elements may detect changes in temperature, pH odour, gas, or the presence of blood or a chemical or biological marker in exudate to indicate a presence of moisture.

Production of the sensor may utilise a range of manufacturing methodologies. One example is screen printing or etching which can be employed to deposit the sensing elements on a suitable substrate. In one form, the sensor may be provided in the form of a flexible printed circuit board formed on a Mylar or other suitable flexible substrate. For three-dimensional arrays, the sensor elements may be deposited on a number of substrate layers which are then bonded into a multilayer liner. For sensor elements incorporated into diapers, depositing the layers on the various absorbent layers of the diaper can be integrated into the diaper manufacturing process.

The sensor elements may be elongate or provided in the form of grids, dots or the like, arranged in a pattern along and/or in the diaper or a pad or liner attachable thereto. By utilising, for example, screen printing or etching techniques, effective patterns can be designed and printed in layers of the sensor quickly and accurately. Advantageously, screen printing can deposit conductive polymers, inks and the like in very fine lines or grids between which exudate including urine and faeces may be absorbed into deeper, more absorbent layers. This enables conductive elements of a sensor to be incorporated into a diaper or absorbent article without significantly affecting the performance of the diaper.

The sensor elements are preferably provided in a quantity and pattern sufficient to enable detection of moisture in different locations in an absorbent article being worn by a user. The pattern may be a two-dimensional pattern in which
5 sensor elements are provided in a single layer or in a three-dimensional pattern. The pattern of sensor elements is preferably such that the elements are focussed in regions of the article where there is a greater likelihood of them being affected by a wetness event. Figure 8 is a schematic drawing of a diaper 800 laid flat, showing one example of a pattern of sensor elements which may
10 be suitable. Each of the sensor elements may be uniquely identified enabling sensor signals to convey to the processor data indicating that wetness is present, as well as the location of the sensor element(s) detecting the wetness. This enables the processor to determine where in the absorbent article and the extent to which the wetness has occurred. Spread of wetness may also be
15 identified.

In one embodiment, the sensor has a plurality of layers and the sensor elements are arranged in a three-dimensional pattern within the layers. A three-dimensional array is advantageous for a number of reasons. Firstly, absorbent
20 articles such as diapers are flexible in nature and therefore prone to folding or scrunching particularly in regions around the legs. To circumvent a problem in which 2 or more conductive elements of a sensor are caused to "short" together as a result of a fold in the article or movement of a wearer, adjacent conductive elements may be placed in alternate layers of the sensor, separated by an
25 electrically insulating permeable layer to prevent shorting in the absence of wetness.

Secondly, by positioning sensor elements in different layers, it is possible for the sensor to convey additional location data to the processor relating to the depth
30 at which moisture is detected. This is particularly important for sophisticated diapers and incontinence garments which are multi-layered in their construction and designed with super absorbent and "wicking" properties to draw wetness away from the wearer and direct it to chambers or zones in the absorbent layers where it is retained. Positioning sensor elements in or near various absorbent

layers of the article can convey further relevant data to the processor which may relate to, for example, the degree of wetness (or fullness) of a storage chamber within a diaper. Also, elements located at various depths allow the system to monitor the absorption of fluid into a diaper. Thus, the sensor will not require
5 'pooling' of moisture to detect wetness. This is especially useful in view of the fact that most modern absorbent garments are manufactured to maximise the absorption of liquid away from the skin.

As indicated above, the sensor elements are arranged in a pattern which
10 maximises the ability to detect relevant data, for use in characterising wetness events. For example, as illustrated in Figure 8, the pattern may provide sensor elements more densely in a region toward the front of the absorbent article (802), to the rear of the absorbent article (804), and around the leg openings (806) and in the centre, between the leg opening (808), where liquid is likely to
15 drain. Positioning the sensor elements in this way improves the detection of urinary wetness which normally occurs toward the front of an absorbent article, detection of faecal wetness which normally occurs to the rear of an article, and detection of wetness resulting from perspiration which can frequently occur, for example, toward the sides in the crotch area near the crease of the wearer's
20 legs, and toward the middle of the diaper.

The sensor may also provide means to detect temperature, pressure, presence of a gas or odour in the absorbent article and/or the presence of a biological or chemical marker indicating presence of bacteria, sugar, parasites or the like in
25 the urine or faeces. This is particularly useful for patients who lack the ability to control where and/or when a voiding event will occur. Data pertaining to these further parameters can also be used, in combination with signals from the conductive elements to further characterise a wetness event, provide a diagnostic indicator, or at least give a carer an early indication that a particular
30 patient is in need of further attention. Other sensor elements may also be incorporated to indicate whether the patient is moving or in a sitting. Lying or standing position.

The sensor signals may be logged regularly, say, every 100 milliseconds or sufficiently frequently to reliably and accurately detect and distinguish an event. Signals received by the processor can reveal data indicating for example (i) detection of wetness and (i) location of the detected wetness. These signals can vary over time, as liquid is absorbed through the diaper and further wetness events occur. By monitoring these signals in time, it is possible for the processor to derive further useful parameters such as volume of exudate in an event and total volume absorbed, using mathematical modelling.

Also, the volume of exudate released can be computed using such factors as the distance between sensor elements detecting the wetness, the rate of transfer of moisture between these elements and the absorption properties of the materials used. These materials may include polymer fibres, natural fibres, gels, textiles, fabrics, papers or a combination of these materials.

The processor may also be programmed with or can interrogate a database of "event signatures" or models characterising certain wetness events and correlate the sensor signals with the event signatures/models to characterise wetness events which are detected. The models may be embodied in any form including mathematical models as described above, graphs or look up tables.

Advantageously, by including laterally placed sensor elements in the sensor pattern, incontinence events can be detected irrespective of whether the patient is in the sitting, lying or standing position. For instance, if the patient is lying on his side, laterally located sensor elements are more likely to detect urinary exudate than the frontal elements which would be activated if the patient was standing or sitting.

Lingering wetness may be indicated by failure of the signal to recover to a normal level. A prolonged high sensor signal value may indicate the presence of faecal matter which, unlike urine, may not be drawn into the absorbent layers of the diaper but remains in contact with the sensor elements. Detection of a faecal event should be accompanied by an alert to a carer to change the diaper so as to avoid prolonged wetness and discomfort. A lingering wetness may also

be indicative of a full diaper, resulting from inability of the diaper to draw any more urine away from the wearer. This condition should also be communicated to a carer.

- 5 The system of the present invention may be utilised with a diaper to be worn by the patient, which diaper has features which enable it to monitor incontinence, particularly urinary incontinence, by, for example, collecting data from the patient wearing the diaper, and transmitting it to a location where such data may be processed. The diaper may also include features which enable samples of,
10 for example, urine, to be withdrawn *in situ* from such a diaper, for testing.

Figure 9 shows a diaper 910 which is adapted to be worn by a patient (not shown). Preferably, the diaper 910 is disposable and/or re-usable, and may have an elasticised waistband 912 and elasticised upper thigh bands 914, 916. The diaper 910 is intended to permit the estimation of the volume of urine
15 flowing from the patient in real time. This is effected by the placing of one or more moisture (wetness) sensors 918 at different locations in the diaper 910. The sensors 918 may form part of a radio transmitting and data capturing arrangement (not shown), such as the one described above.

The sensors 918 may constituted by conductive inks or other means adapted to
20 detect the presence of moisture. The sensors 918, are connected to the aforementioned arrangement, which may be a purpose designed continence management system which captures the data captured by the sensors 918, which data is recorded via e.g. radio transmission or the like to the processor described above. Some of the data may also be transmitted to nursing staff or
25 a nursing station responsible for the management of the incontinence episode in an appropriate manner for the patient or resident in question.

The conductive inks used in the sensors 918 are preferably based on low-cost materials such as carbon, formulated on the carbon content of different concentrations and composition, to achieve the most appropriate sensitivity for
30 moisture detection. Prior art conductive units are silver-based, and accordingly are typically too expensive for use in a disposable diaper.

The choice of carbon or a similar inert substance will reduce the likelihood of interference with chemical markers, which may be incorporated into the sensors 918, for the detection of clinically relevant substances of the type referred to earlier in this specification. Information captured by the chemical markers may
5 be processed for improved management of clinical conditions of residents and patients by medical or nursing staff.

Preferably, the conductive ink will be such that rapid drying or curing will be achieved to enable manufacture of disposable diapers 910 to be carried out at rates consistent with the production of existing and future diapers, presently in
10 the order of 400 diapers per second. The manufacturing process may be carried out using ultraviolet light in a manner similar to that used in rapid curing of dental materials for various dental procedures such as dental fillings.

In a preferred arrangement, the volume of urine passed by the resident or patient, preferably in a unit of time, will be established using a mathematical
15 model computed by using such factors as the distance between sensors 918, the rate of transfer of moisture between sensors 918, and the absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres.

Turning now to Figure 10, a diaper or the like 1020 which may fundamentally be
20 similar to the diaper 910 of Figure 9, and which is adapted to be worn by a patient or resident suffering from some form of incontinence. Preferably, the diaper 1020 is disposable and/or re-usable, and preferably has an elasticised waistband 1022 and elasticised upper thigh bands 1024, 1026.

The diaper 1020 has a sleeve 1028 located preferably in the area of the diaper
25 1020 close to the pubic area of the patient or resident. The sleeve 1028 is intended to house a diagnostic strip or the like 1030. Such diagnostic strips 1030 may be of the Multistix/Combistix type or similar to other strips which are able to detect relevant substances in urine, for example blood, sugar, nitrites, leucocytes, urea, specific gravity, protein, and other substances. As some of the

chemical sensors on the strips 1030 use and are derived from blood products, the sleeve 1028 will protect the skin of the wearer from such blood derived products and thus accidental infection with hepatitis B, hepatitis C or HIV.

It is considered that as the information to be obtained from the diagnostic strips 1030 may need to be obtained within certain time frames, the sleeve 1028 will need to allow for a sufficient volume of urine to be captured so that the urine may make contact with the strip 1030, and for radio transmission of data to take place within the required time frame.

Figures 11a and 11b show front and rear views of an exemplary sleeve 1128 for a diagnostic strip 1130. The sleeve 1128 is secured to diaper 920, 1020 as will be described hereinafter, and is designed and constructed of materials which will attract and capture urine from the patient or resident. This will expose the chemical sensors on the strip 1130 to the collected urine.

The front 1132 of the sleeve 1128 may be provided with a V-shaped notch 1134 for ease of insertion of a diagnostic strip 1130. Pores and channels 1136 may be provided to facilitate the drawing in of the urine to the interior of the sleeve 1128, effectively "sucking up" the urine. The rear 1138 of the sleeve 1128 may be provided with adhesive material 1140 for attaching the sleeve 1128 to the diaper 1120 or pad, in much the same manner as used in feminine hygiene products.

A sleeve 1128 will allow urine to be captured in sufficient volume to permit the detection of relevant clinical substances. The interpretation of the results of such detection are preferably based upon a recalibration of what may be regarded as normal or abnormal, compared to existing "dipsticks", which have established normal and abnormal values for interpretation. This re-standardising may be required to take account of any alteration which may occur in the components in the urine samples, as a result of the present invention. For example, diaper fibres may trap some white blood cells, so that a new "normal value" may be needed to be established to cater for such a

possibility. As a consequence, a new lower value for the number of leucocytes in a sample may be required.

Another example relates to the test for the albumen:creatinine ratio in a spot urine sample. A level of 0.7 mg/mmol corresponding to a urinary excretion rate of more than 5 mgm/min would indicate a high-risk (in cardiovascular terms) patient requiring aggressive treatment. This marker of arterial damage may be considered with raised cholesterol and hypertension as a serious risk factor for cardiovascular disease. Such values would be revised if necessary for the purposes of the present invention.

10 The sleeve operates as follows. Urine is drawn into the sleeve 1128 via capillary action, osmosis and semipermeable membrane processes, thereby bringing the urine into contact with a diagnostic strip 1130, which may be a proprietary strip such as marketed under the Bayer and Roche brands, to enable the "reading" to take place in a timely fashion. The carer or nurse will
15 have been alerted to the availability of the urine sample through the radio-based system and software-based system described earlier in this specification.

Patients or residents may be required to take standard known quantities of substances such as creatinine to carry out reliable, accurate tests which the incontinence management system is able to interpret reliably. Such ingested
20 substances may be excreted in an unmetabolised form, for example, as creatinine asparagine, or may be actively metabolised and measured as a metabolite in the urine.

The embodiment of Figures 12 and 13 of the present invention makes possible the interpretations of findings in near real time, as the requirement of testing
25 fresh, recently passed, urine is essential for the most accurate interpretations to take place.

In Figure 12 there is shown a pad 1242 which preferably is adapted to be attached to a diaper (not shown) of a neonate, baby or a child, more preferably by adhesive means such as 1244. The pad 1242 itself is preferably formed

from an absorbent material 1246 such as a sponge or sponge-like material e.g. containing super absorbent particles, to take up urine excreted by the baby. The pad 1242 may also preferably be fitted with a transmitter 1248 for transmitting data to the system(s) described previously in this specification.

- 5 One example of such a signal would be a signal representative of the fact that voiding had taken place. This may be accomplished by linking the transmitter 1248 with a wetness sensor (not shown).

Currently, there are three existing sample collection methods, where the collection samples are carried out by "catch" techniques, adhesive collection
10 bags, or suprapubic bladder puncture. There are also "time interval" tests, such as 1-hour and 2-hour tests to establish levels of incontinence during the stated time intervals, in which conventional pads are simply weighed to determine the volume of urine. These are termed "pad tests".

The pad 1242 shown in Figure 12 is much more sophisticated. It preferably
15 comes in three versions. The first version would be a "wetness only" signalling pad, where a parent or nurse would be alerted in real time of passage of urine, would collect the pad and place it in a suitable container to be sent promptly to the microbiology and pathology lab for testing, or would draw up the urine via a syringe for placement in a container, with the container being sent to the lab.

20 The second type involves the pad 1242 having a collecting chamber (not shown) incorporated therein, into which urine has been drawn. This chamber is preferably removable, so that it may be removed when a predetermined amount of urine, or urine passed in a predetermined period of time has been passed, and sent to the microbial/pathology lab.

25 The third type of pad 1242 would have a chamber such as that described in relation to the second type, but which would include diagnostic strips of the type and purpose described hereinbefore in relation to Figures 9 to 11b. The design of the collection chamber, sleeve or pocket will be such that it will collect urine for dipstick testing, for collection of samples to be transported for

pathology/bacteriology testing, or *in situ* testing using the new sensors designed for the incontinence management system.

The collection chamber, sleeve or pocket will be designed in conjunction with the diaper to which it is attached, which diaper draws and feeds the urine into
5 the chamber, to maximise the volume of urine collected, when only small voids have occurred.

Alternatively, urine may be expunged from a urine-soaked pad 1242 via a special container which may expel urine by the use of a plunger (not shown), which may be compared to the plunger in a coffee plunger, which is able to
10 force urine into a sealed compartment (not shown), separate from the pad 1242.

The pad 1242 may have capillary channels (not shown, but preferably similar to channels 1136 of Figure 11a, to draw the urine towards the collection chamber. The pad 1242 and/or diaper containing the pad 1242 may also preferably use materials designed for osmosis, capillary action or other manner of providing
15 directional flow of urine to assist in the transfer of the urine to a location where it is required. Figure 13 shows an alternative pad 1350, which may be generally similar to pad 1242 of Figure 12, but which has a generally cylindrical shape.

Reference is now made to the extension of the present invention to other bodily fluids and exudates from the body of a person. In the case, for example, of
20 serous and other exudates, a dressing for a wound are preferably provided such that information about the wound may be relayed via sensors located on or in association with the dressing, which would otherwise be difficult to determined because conventional dressings or casts would be in the way.

It may also be the intention of the present invention to provide sensors of the
25 dipstick and/or electronic type for dressings on wounds. Additional components, ions and chemical markers of bodily fluids or exudates from the body, may be detected *in situ* or via the sensors located on or in association with the sensors. Presently, such body products are tested away from the patient in biochemical

and bacteriological laboratories. The sensor-equipped dressings may also be used to inform nursing staff of ooze, and content.

It is to be understood that various modifications, additions and/or alterations
5 may be made to the parts previously described without departing from the ambit
of the present invention as defined in the claims appended hereto.

Claims:

1. A moisture monitoring system for monitoring wetness in one or more absorbent articles, the system including:
 - 5 an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article;
 - a processor for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article; and
 - 10 user interface for communicating with a user of the system.
2. A moisture monitoring system according to claim 1 wherein the processor executes an algorithm to devise a mathematical model for characterising a wetness event in an absorbent article.
- 15 3. A moisture monitoring system according to claim 1 wherein the processor executes an algorithm to perform the analysis and wherein the algorithm applies uses the sensor signals and a pre-determined mathematical model to characterise a wetness event in an absorbent article by determining one or
20 more of:
 - (i) an estimated volume of exudate in a wetness event; and
 - (ii) the nature of exudate in a wetness event.
4. A moisture monitoring system according to claim 1 wherein the processor
25 uses sensor signals and/or variables derived from the sensor signals to derive one or more parameters suitable for use in a mathematical model for characterising a wetness event.
5. A moisture monitoring system according to claim 3 wherein the algorithm
30 applies variables derived from the one or more sensor signals to a pre-determined mathematical model to characterise a wetness event.
6. A moisture monitoring system according to claim 3 wherein the one or more sensor signals are indicative of one or more of:

- (i) conductivity of the exudate;
- (ii) temperature of the exudate;
- (iii) location of the exudate;
- (iv) pH of the exudate;
- 5 (v) pressure within the absorbent article;
- (vi) odour within the absorbent article;
- (vii) presence of a gas in the absorbent article;
- (viii) presence of blood and/or a biological marker and/or a or chemical
marker in the exudate.

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7. A moisture monitoring system according to claim 4 wherein variables derived from the sensor signals are selected from the group including:

- (i) area under a sensor signal curve;
- (ii) highest sensor signal value in a predetermined time period;
- 15 (iii) maximum value of a leading edge of the sensor signal;
- (iv) rate of decay of sensor signal after a leading edge;
- (v) a volume estimated in a previous wetness event;
- (vi) time of onset of a wetness event;
- (vii) time of termination of a wetness event; and
- 20 (viii) duration of a wetness event;
- (ix) time of day of a wetness event; and
- (x) time elapsed since last wetness event.

8. A moisture monitoring system according to claim 1 wherein the processor
25 is configured to determine one or more of:

- (a) a likelihood of an imminent wetness event;
- (b) an estimate of when a wetness event is likely to occur;
- (c) an estimate of a degree of fullness of an absorbent article; and
- (d) an estimate of when an absorbent article is likely to reach its
30 absorbent capacity.

9. A moisture monitoring system claim 1, wherein the user interface includes a wireless transmitter configured to transmit a signal to a user of the

system to indicate that a predetermined volume of wetness has been detected in an absorbent article.

10. A moisture monitoring system according to claim 1 wherein the processor
5 is configured to provide a toileting or voiding diary.

11. A moisture monitoring system according to claim 3 wherein the processor
is configured to derive a toileting or voiding schedule for an individual, based on
wetness events monitored using the monitoring system.

10

12. A moisture monitoring system according to claim 11 wherein the system
is configured to predict, based on a derived toileting or voiding schedule, when
an individual is likely to experience a wetness event which meets pre-defined
criteria for manual checking.

15

13. A moisture monitoring system according to claim 1 wherein the system is
further adapted to communicate automatically, an alert to a carer when one or
more pre-defined criteria for manual checking are satisfied.

20 14. A moisture monitoring system according to claim 1 wherein the processor
is configured to classify a possible form of incontinence suffered by a patient
monitored by the system, the form of incontinence being selected from the
group including urinary, fecal, dribble, stress, overflow, urge, mixed urinary
(MUI), total and functional incontinence.

25

15. A moisture monitoring system according to claim 1 wherein the processor
is configured to recognise and/or predict lingering wetness in a region of an
absorbent article.

30 16. A moisture monitoring system according to claim 1 wherein the processor
is affixable to a sensor, an absorbent article or to a garment worn by a wearer of
an absorbent article.

17. A moisture monitoring system according to claim 1 wherein the processor is incorporated into a central monitoring station adapted to receive sensor signals from a plurality of sensors associated with one or more absorbent articles.

5

18. A moisture monitoring system according claim 1 including a pre-processor associated with a sensor of an absorbent article.

19. A moisture monitoring system according to claim 3, adapted to
10 reconfigure the one or more mathematical models for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type, by:

for a training period using the particular individual, the different sensor type or the different absorbent article type, monitoring wetness at regular
15 intervals by obtaining sensor signals and obtaining observation data; and

reconfiguring the mathematical model so that there is satisfactory correlation between the estimates produced using the sensor signals and the reconfigured mathematical model, and the observation data obtained during the training period.

20

20. A moisture monitoring system according to claim 19 wherein reconfiguring a mathematical model involves determining one or more new parameters for the mathematical model.

21. A moisture monitoring system according to claim 19 wherein
25 reconfiguring a mathematical model involves application of a linear regression algorithm.

22. A moisture monitoring system according to claim 19 wherein the
30 observation data includes measurements indicating an amount of wetness in the absorbent article and time of measurement.

23. A moisture monitoring system according to claim 19 wherein the observation data includes one or more of:

demographic information; and
patient information.

24. A sensor for use with an absorbent article being monitored for wetness,
5 the sensor including a plurality of sensor elements arranged in a pattern which
provides an improved ability to detect wetness.

25. A sensor according to claim 24 wherein the sensor elements are
arranged in a pattern in which there are more sensor elements in regions
10 having higher propensity for variable moisture or temperature.

26. A sensor according to claim 24 wherein, when applied to or incorporated
into an absorbent article, one or more sensor elements extend beyond an edge
thereof.

15 27. A sensor according to claim 26 wherein, when applied to or incorporated
into an absorbent article, one or more sensor elements extend beyond a front
edge thereof.

20 28. A sensor according to claim 24 further including a connector for
connecting the sensor elements to a signal receiver unit.

29. A sensor according to claim 24 further including a cover layer over the
sensor elements, the cover layer extending beyond an edge of the absorbent
25 article and including means for enclosing a signal receiver unit attachable to
one or more of the sensor elements.

30. A sensor according to claim wherein, when applied to or incorporated
into an absorbent article, one or more sensor elements are arranged for
30 connection to a signal receiver unit outside the absorbent article.

31. A sensor according to claims 28 wherein the signal receiver unit includes
storage means for storing sensor signals collected over a period of time.

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32. A sensor according to claims 28 wherein the signal receiver unit includes means for receiving data relating to a patient's toileting activities.

33. A sensor according to claim 24 wherein the pattern includes sensor elements positioned toward the sides of the absorbent article, near an opening for receiving a leg of the wearer.

34. A sensor according claim 24 wherein the pattern includes sensor elements located at two or more depths of the absorbent article.

35. A sensor according to claim 24 wherein the sensor includes a sensor substrate, the sensor substrate having one or more channels arranged between adjacent elements of the sensor.

36. A sensor according to claim 35 for use with an absorbent article having super absorbent material arranged in the article so as to draw fluid from the one or more channels in the sensor substrate.

37. A sensor according to claim 24 wherein the sensor is provided on a flexible substrate affixable, by adhesive or other means, to an absorbent article wearable by a user.

38. A sensor according to claim 24 wherein the sensor elements detect wetness at various identifiable locations with respect to the absorbent article, the locations selected from the group including:

- (a) toward the front of the absorbent article;
- (b) toward the rear of the absorbent article;
- (c) toward a side of the absorbent article; and
- (d) substantially centrally of the absorbent article.

30

39. A sensor according to claim 24 wherein the pattern of sensor elements facilitates improved detection of moisture from a user in a range of positions including standing, sitting, lying prone, lying supine and lying on the side.

40

40. A sensor according to claim 24 wherein the sensor elements are arranged to detect spread of moisture from a wetness event in two or more directions.

5 41. A sensor according to claim 24 wherein the sensor pattern includes one or more of:

elongate sensor elements;
sensor elements arranged in a grid; and
an array of sensor element dots.

10

42. A sensor according to claim 24 wherein the sensor includes sensor elements for detecting one or more of electrical conductivity, temperature, pressure, pH, odour, gas and presence of a biological or chemical marker in exudate and location of exudate.

15

43. A method for monitoring moisture in an absorbent article including the steps of:

- (a) receiving one or more sensor signals associated with the absorbent article, the sensor signals indicating wetness in the absorbent article;
- 20 (b) applying one or more sensor signals to a predetermined mathematical model for characterising a wetness event; and
- (c) based on the mathematical model, characterising a wetness event in the absorbent article.

25 44. A method for monitoring moisture according to claim 43 wherein characterising a wetness event involves ascertaining one or more of an estimated volume of exudate in a wetness event and the nature of the exudate.

45. A method for monitoring moisture according to claim 43 further including
30 the step of automatically notifying a user if one or more predetermined notification criteria are met.

46. A method for monitoring moisture according to claim 43 wherein the predetermined mathematical model has variables derived from the one or more sensor signals.

5 47. A method for monitoring moisture according to claim 43 wherein the sensor signals are indicative of one or more of:

- (i) conductivity of the exudate;
- (ii) temperature of the exudate;
- (iii) location of the exudate;
- 10 (iv) pH of the exudate;
- (v) pressure within the absorbent article;
- (vi) odour within the absorbent article;
- (vii) presence of a gas in the absorbent article; and
- (viii) presence of blood and/or a biological marker and/or a chemical
- 15 marker in the exudate.

48. A method for monitoring moisture according to claim 46 wherein the variables derived from the sensor signals are selected from the group including:

- (i) area under a sensor signal curve;
- 20 (ii) highest sensor signal value in a predetermined time period;
- (iii) maximum value of a leading edge of the sensor signal;
- (iv) rate of decay of sensor signal after a leading edge;
- (v) a volume estimated in a previous wetness event;
- (vi) time of onset of a wetness event;
- 25 (vii) time of termination of a wetness event; and
- (viii) duration of a wetness event;
- (ix) time of day of a wetness event; and
- (x) time elapsed since last wetness event.

30 49. A method for monitoring moisture according to claim 43 further including the step of maintaining a toileting or voiding diary, being a log of monitored wetness events.

50. A method of monitoring moisture according to claim 43 further including the step of deriving a toileting or voiding schedule for an individual, based on wetness events monitored using the monitoring system.

5 51. A method of monitoring moisture according to claim 50 further including the step of predicting, based on a derived toileting or voiding schedule, when an individual is likely experience a wetness event which meets pre-defined criteria for manual checking.

10 52. A method of monitoring moisture according to claim 43 further including the step of reconfiguring the mathematical model for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type, by:

for a training period using the particular individual, the different sensor
15 type and/or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data; and

reconfiguring the mathematical model so that there is satisfactory
correlation between the estimates produced using the sensor signals and the
reconfigured mathematical model, and the observation data obtained during the
20 training period.

53. A method of monitoring moisture according to claim 52 wherein reconfiguring a mathematical model involves determining new parameters for the mathematical model.

25

54. A method of monitoring moisture according to claim 52 wherein reconfiguring a mathematical model involves application of a linear regression algorithm.

30 55. A method of monitoring moisture according to claim 52 wherein the observation data includes measurements indicating an amount of wetness in the absorbent article and time of measurement.

56. A method of monitoring moisture according to claim 52 wherein the observation data includes one or more of demographic information and patient information.

5 57. A diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper includes a sleeve for the insertion of a diagnostic strip.

58. A diaper according to claim 57 characterised in that said sleeve is
10 located on said diaper close to, in use, the pubic area of a wearer.

59. A diaper according to claim 57, characterised in that said diaper has means designed to direct fluids excreted by said person, to said sleeve.

60. A diaper according to claim 57, characterised in that said sleeve is provided with a V-shaped notch to facilitate the insertion of a diagnostic strip.

15 61. A diaper according to claim 57, characterised in that said sleeve is attachable to said diaper by adhesive material.

62. A diaper according to claim 59, characterised in that said means designed to direct fluids excreted by said person, to said sleeve, is constituted by pores and/or channels.

20 63. A diaper according to claim 62, characterised in that said pores and/or channels are located around the periphery of said sleeve.

64. A diaper according to claim 57, characterised in that sleeve is adapted to retain a predetermined amount of exudate to facilitate contact of said exudate with said strip.

25 65. A diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person,

characterised in that said diaper is provided with a plurality of sensors at different locations in said diaper.

66. A diaper according to claim 65, characterised in that said sensors are wetness sensors.

5 67. A diaper according to claim 66, characterised in that said sensors are adapted to permit the estimation of the volume of exudate flowing from the patient in real time.

68. A diaper according to claim 67, characterised in that the volume of exudate passed by the person wearing said diaper, preferably in a unit of time,
10 is established using a mathematical model computed by using such factors as the distance between said sensors, the rate of transfer of moisture between said sensors, and the absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres.

15 69. A diaper according to claim 65, characterised in that data from said sensors is transmitted using radio technology, and in that said data is processed using software running the aforementioned mathematical model.

70. A diaper according to claim 65, characterised in that each of said sensors is constituted by conductive inks.

20 71. A diaper according to claim 65, characterised in that the spacing of said sensors is at different thicknesses in material forming at least a part of said diaper.

72. A pad for use with a diaper, said pad being associated with transmitting means, for transmitting signals representative of an aspect of fluids absorbed by
25 said pad, to a remote location.

45

73. A diaper according to claim 72, characterised in that said pad includes a chamber for collection of said fluids.

74. A diaper according to claim 73, characterised in that said chamber is removable.

5 75. An incontinence management system or a system for the management of other exudates from the body of a person, characterised by an article adapted to be worn by the person, sensing means associated with said article and adapted to sense a condition, and transmitting means adapted to transmit a signal generated by said sensing means to a location.

10 76. An incontinence management system according to claim 75, characterised in that said system also includes means for processing said signal.

77. An incontinence management system according to claim 75, characterised in that said sensing means is a plurality of sensors, arranged
15 spatially in said article.

78. An incontinence management system according to claim 77, characterised in that said spatial arrangement includes the spacing of sensors at different thicknesses in material forming at least a part of said article.

79. An incontinence management system according to 75, characterised in
20 that said article is a diaper.

Abstract

An incontinence management system for monitoring wetness in one or more absorbent articles, includes input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article, processor for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article and user interface for communicating with a user of the system. A mathematical model is used to characterise wetness events, receiving as inputs variables derived from sensor signals and optionally, patient and demographic data. The mathematical model can be configured and/or re-configured utilising observation data obtained while monitoring a patient for wetness. A diaper for use with such as system is also disclosed.

15

[Figure 5b]

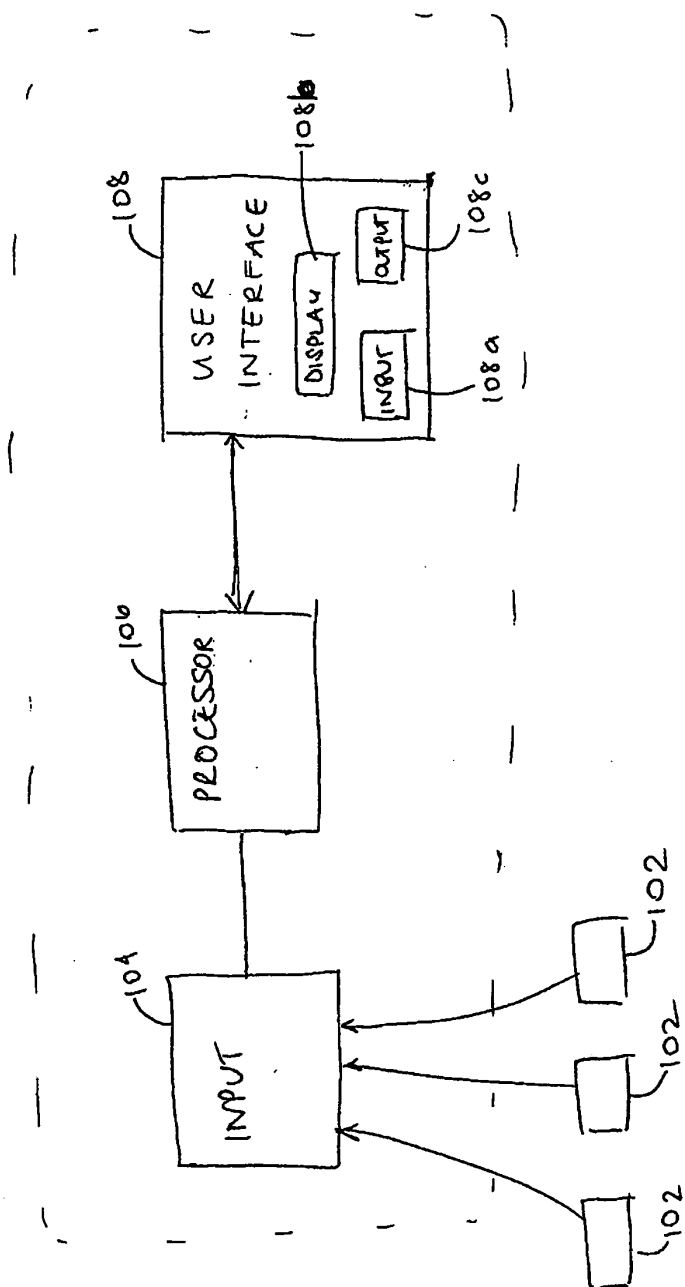


FIGURE 1

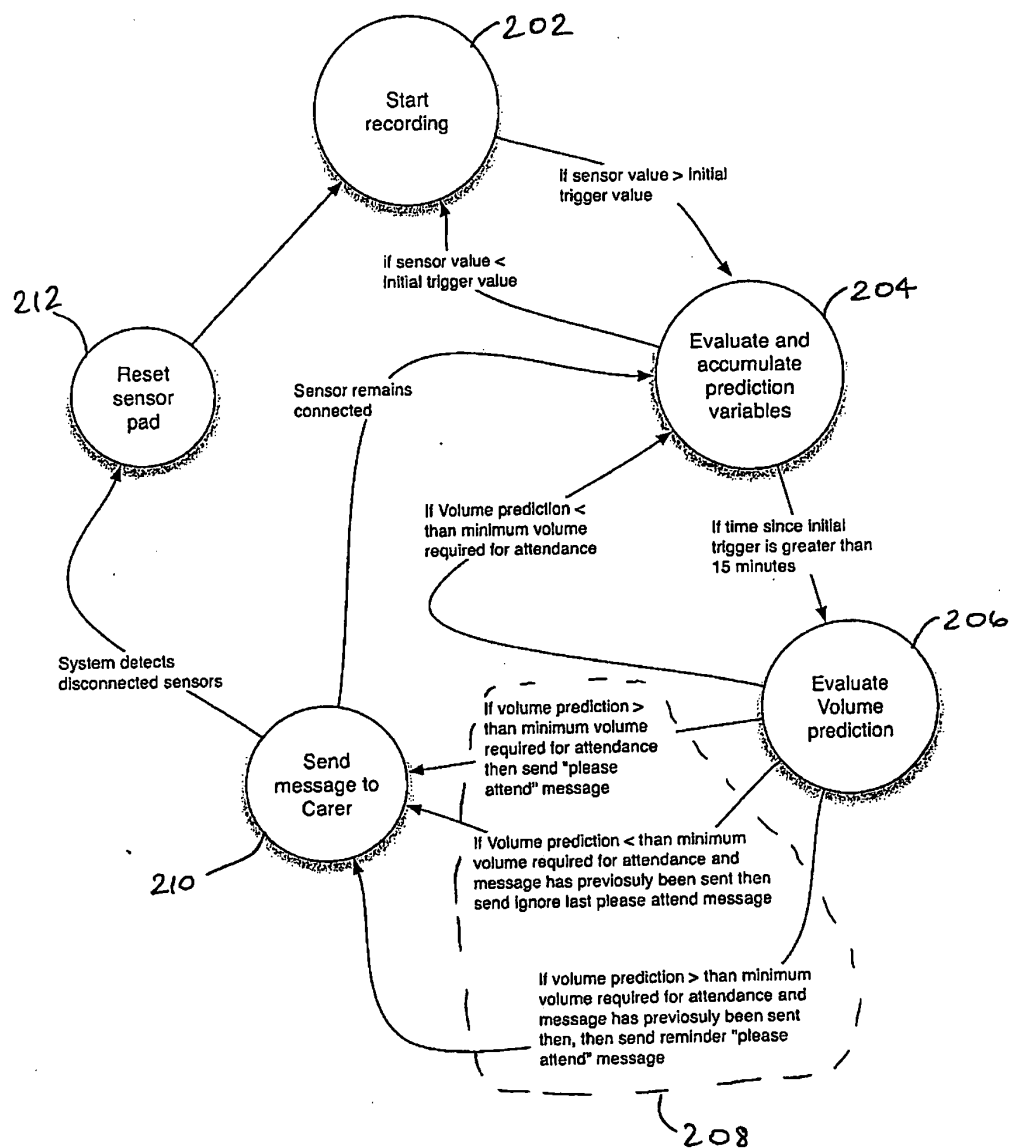


FIGURE 2

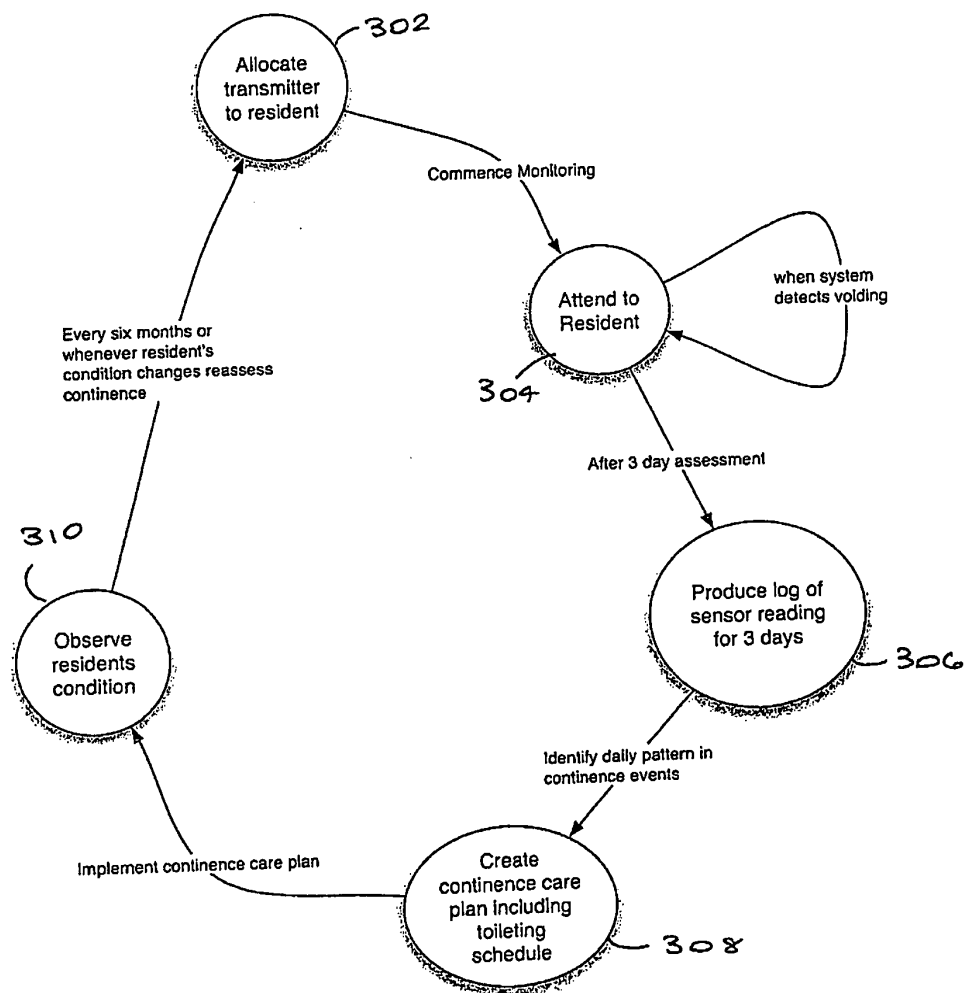


FIGURE 3

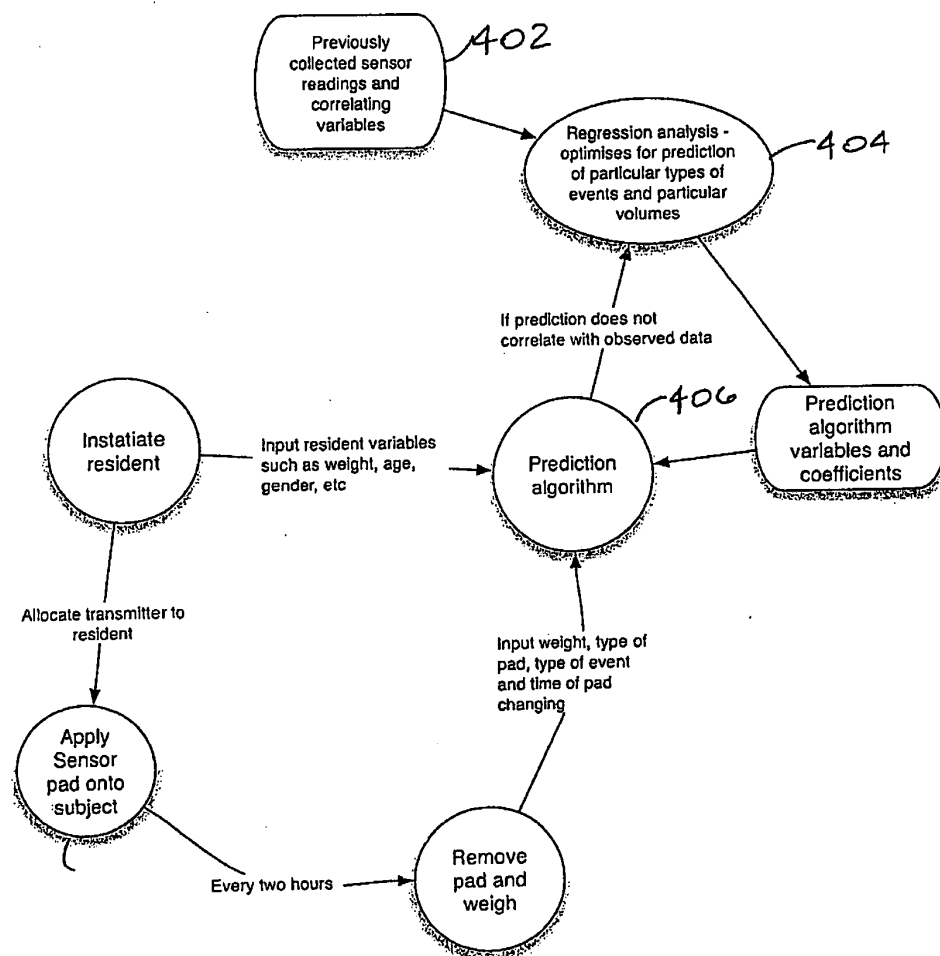


FIGURE 4

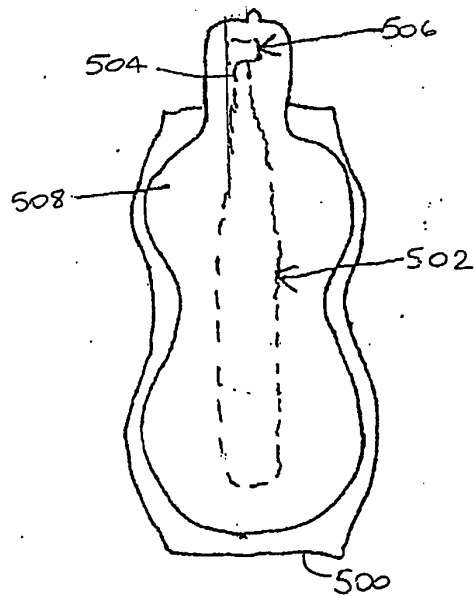


FIGURE 5A

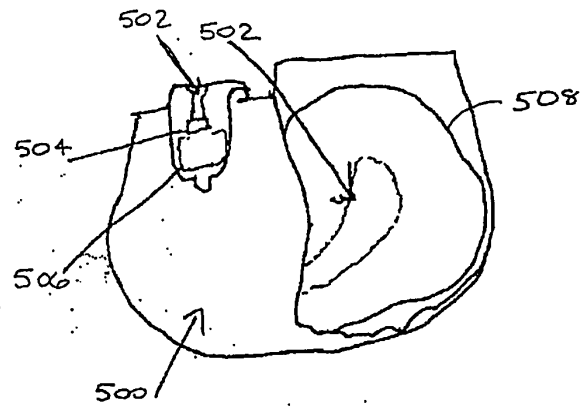


FIGURE 5B

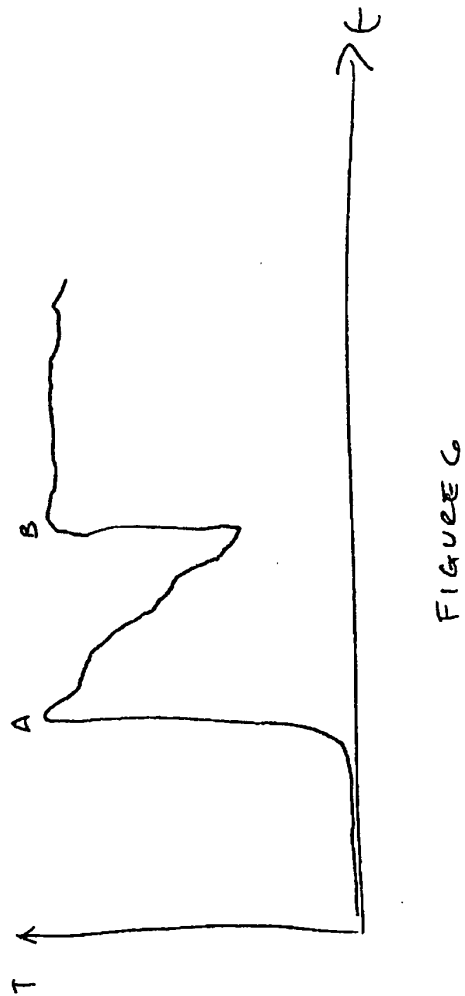


FIGURE C

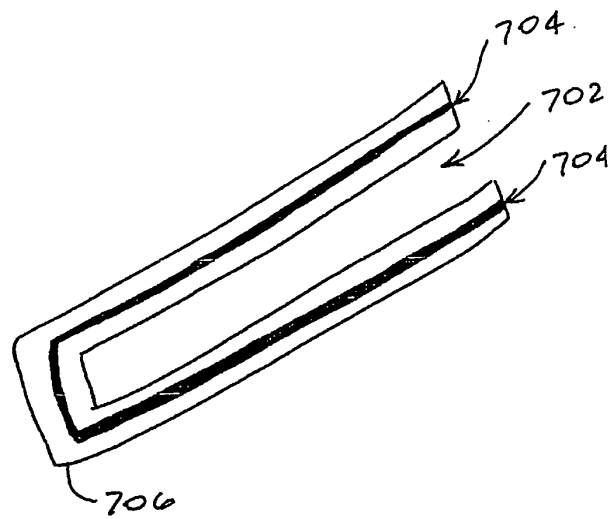


FIGURE 7

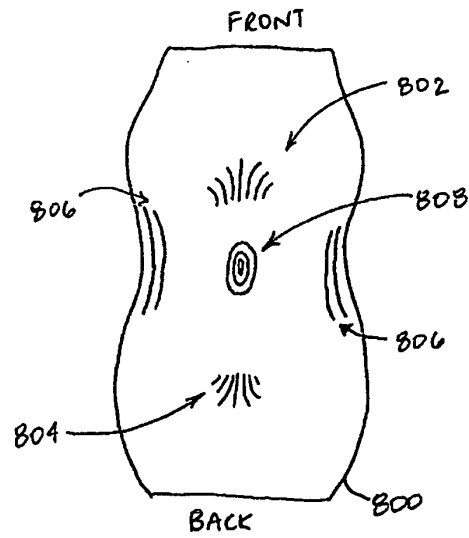
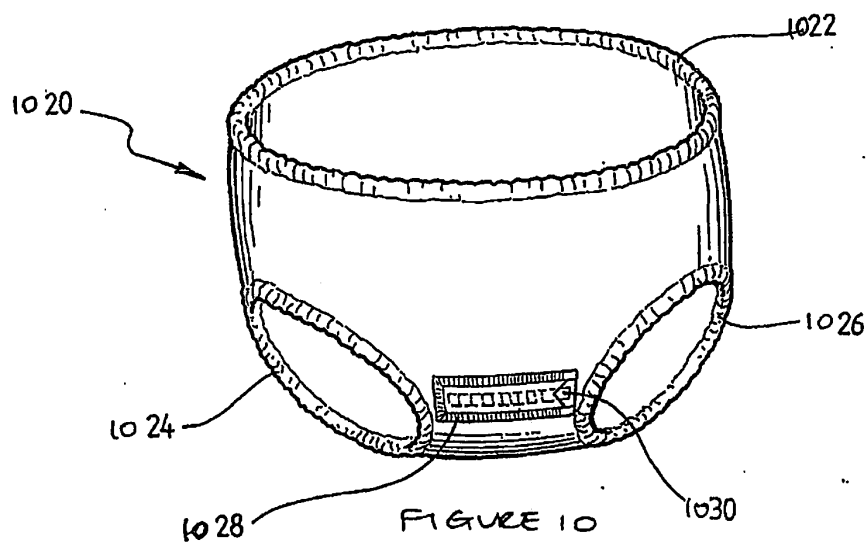
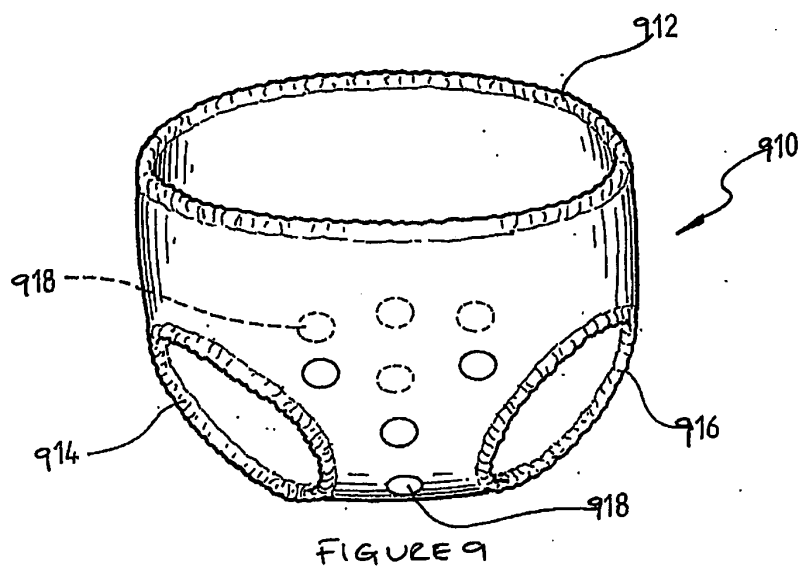


FIGURE 8



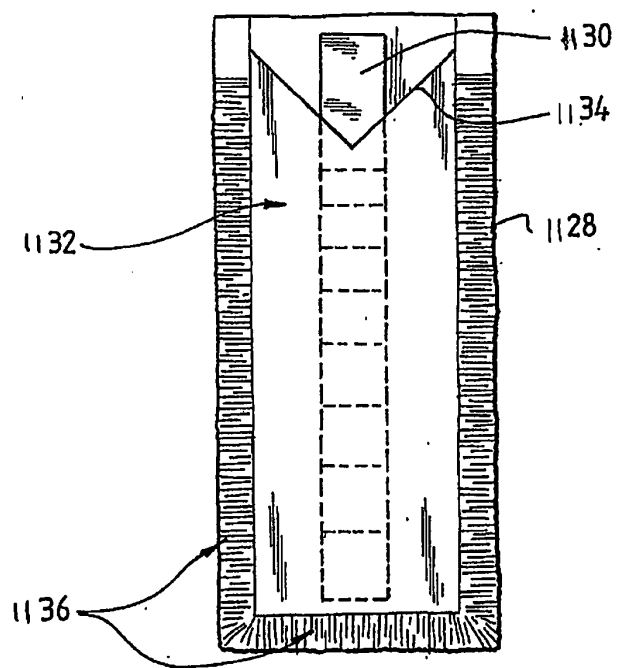


FIGURE 11a

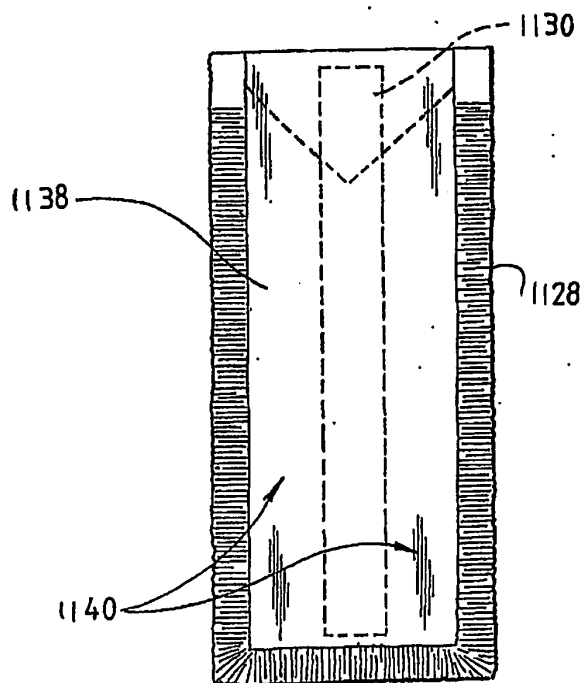
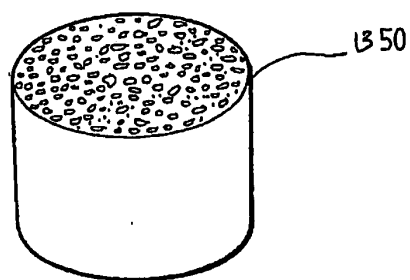
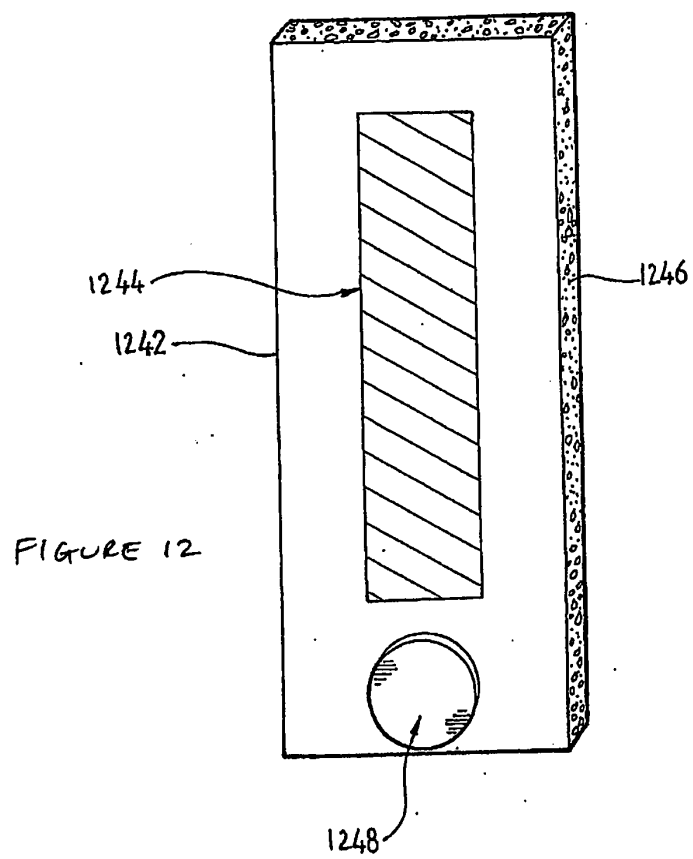


FIGURE 11b



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: BERGMAN et al.

Serial No.: New

Filing Date: 2 May 2007

For: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Prior to initial examination, please amend the above-identified application as follows:

IN THE SPECIFICATION

On page 1, immediately following the title, please insert the following sentence:

This is a Continuation-in-Part of PCT/AU2005/001667 filed 28 October 2007 and published in English.

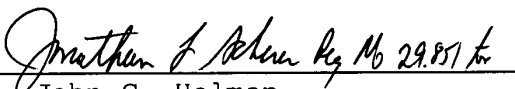
REMARKS

The foregoing Preliminary Amendment is requested in order to place the application in better form for examination.

Early action on the merits is respectfully requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By 
John C. Holman
Reg. No. 22,769

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666

Atty. Docket: P71951US0
Date: 5/2/2007
JCH/gc



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U.S. PTO
11/797352
05/02/2007

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Firm e-mail: ip@jhip.com

May 2, 2007

Atty. Docket No.: P71951US0
CUSTOMER NUMBER: 00136

Mail Stop PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith for filing is a CONTINUATION-IN-PART application of pending PCT/AU2005/001667 which has designated the U.S., filed on 28 October 2005 of

Frederick BERGMAN (deceased)
David Albert BARDA, Docklands, AUSTRALIA;
Daniel WEINSTOCK, Caulfield South, AUSTRALIA;
Remi GUIBERT, Mount Martha, AUSTRALIA;
Maria C. RODDA, Mount Eliza, AUSTRALIA; and
Guy EITZEN, Wheelers Hill, AUSTRALIA

for **INCONTINENCE MANAGEMENT SYSTEM AND DIAPER** and which is hereby incorporated by reference. The application comprises a 46-page specification, including 79 claims (8 independent) and Abstract and 11 sheets of drawings.

Accompanying the application for filing is:

Preliminary Amendment

A certified copy of **Australian** Provisional Application No. **2006902251** filed **2 May 2006**, and **Australian** Application No. **2004906315** filed **3 November 2004**, will be filed in due course, the priority of which is claimed under 35 U.S.C. §119 and which is hereby incorporated by reference.

This application is being filed under 37 C.F.R. §1.53(f) (without Declaration or Filing Fee). The required Declaration and Filing Fee will be filed subsequently. A duplicate copy of this sheet is enclosed.

Should a fee be necessary to obtain a filing date, e.g. paying the basic fee for nationalizing a PCT application, the Commissioner is hereby authorized to charge payment of any fees set forth in §§1.16, 1.17 or 1.492 during the pendency of this application, or credit any overpayment, to Deposit Account No. 06-1358. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
JACOBSON HOLMAN PLLC

By Jonathan L. Scherer Reg. No. 22,769 for
John C. Holman
Reg. No. 22,769

JCH/gc

Harvey B. Jacobson, Jr. John Clarke Holman Simor L. Moskowitz Allen S. Melser Michael R. Slobasky Marsha G. Gentner Jonathan L. Scherer George W. Lewis
William E. Player Philip L. O'Neill Linda J. Shapiro Leesa N. Weiss Suzin C. Bailey*
Matthew J. Cuccias Joseph G. Contrera John C. Luce Jiwen Chen* Robert S. Pierce*
Of Counsel: Nathaniel A. Humphries

* bar other than D.C.

JA0087

5.2.07

PTO/SB/06 (12-04)

Approved for use through 7/31/2006. OMB 0651-0032

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PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/797,352	
APPLICATION AS FILED – PART I						
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OTHER THAN SMALL ENTITY						
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))						300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))						500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))						200
TOTAL CLAIMS (37 CFR 1.16(i))	79	minus 20 =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	7	minus 3 =				
APPLICATION SIZE FEE (37 CFR 1.16(s))				X\$ 25		X\$50
				X\$100		X\$200
				180		360
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				TOTAL	0	TOTAL
						4750
* If the difference in column 1 is less than zero, enter "0" in column 2.						
APPLICATION AS AMENDED – PART II						
(Column 1)		(Column 2)		(Column 3)		
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)
	Total (37 CFR 1.16(i))	Minus **	=	X =		X =
	Independent (37 CFR 1.16(h))	Minus ***	=	X =		X =
	Application Size Fee (37 CFR 1.16(s))					
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			180		360
			TOTAL		TOTAL	
			ADD'T FEE		ADD'T FEE	
(Column 1)		(Column 2)		(Column 3)		
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)
	Total (37 CFR 1.16(i))	Minus **	=	X =		X =
	Independent (37 CFR 1.16(h))	Minus ***	=	X =		X =
	Application Size Fee (37 CFR 1.16(s))					
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			N/A		N/A
			TOTAL		TOTAL	
			ADD'T FEE		ADD'T FEE	
<p>* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.</p> <p>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".</p> <p>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".</p> <p>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.</p>						

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION AS FILED – PART I						
(Column 1)		(Column 2)		SMALL ENTITY		OR
OTHER THAN SMALL ENTITY						
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	RATE (\$)	FEE (\$)
BASIC FEE (37 CFR 1.16(a), (b), or (c))						300
SEARCH FEE (37 CFR 1.16(k), (i), or (m))						500
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))						200
TOTAL CLAIMS (37 CFR 1.16(i))	79	minus 20	59	X\$ 25	X\$50	2950
INDEPENDENT CLAIMS (37 CFR 1.16(h))	7	minus 3	4	X\$100	X\$200	800
APPLICATION SIZE FEE (37 CFR 1.16(s))						
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))			180		360	
			TOTAL		TOTAL	4750
* If the difference in column 1 is less than zero, enter "0" in column 2.						
APPLICATION AS AMENDED – PART II						
(Column 1)		(Column 2)		(Column 3)		
AMENDMENT A	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	SMALL ENTITY		OR
	Total (37 CFR 1.16(i))	Minus **	=	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)
	Independent (37 CFR 1.16(h))	Minus ***	=	X =		X =
	Application Size Fee (37 CFR 1.16(s))			X =		X =
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			180		360
			TOTAL		TOTAL	
			ADD'T FEE		ADD'T FEE	
(Column 1)		(Column 2)		(Column 3)		
AMENDMENT B	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	SMALL ENTITY		OR
	Total (37 CFR 1.16(i))	Minus **	=	RATE (\$)	ADDITIONAL FEE (\$)	RATE (\$)
	Independent (37 CFR 1.16(h))	Minus ***	=	X =		X =
	Application Size Fee (37 CFR 1.16(s))			X =		X =
	FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))			N/A		N/A
			TOTAL		TOTAL	
			ADD'T FEE		ADD'T FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
 ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
 *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
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APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =		OR	X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =			X \$ =				
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	05/02/2007	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
Total (37 CFR 1.16(i))	*	79	Minus	** 79	=	0	OR	X \$ =		
Independent (37 CFR 1.16(h))	*	7	Minus	*** 7	=	0	OR	X \$ =		
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)		
Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	OR	X \$ =			
Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	OR	X \$ =			
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE	OR	TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

Legal Instrument Examiner:
DONNA D. SMALLS-LOGAN

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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
11/797,352	05/02/2007	3761	0.00	P71951US0	79	7

CONFIRMATION NO. 6338

FILING RECEIPT

136
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
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 WASHINGTON, DC20004

Date Mailed: 05/25/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Frederick Bergman, Residence Not Provided,
 Deceased;
 David Albert Barda, Docklands, AUSTRALIA;
 Daniel Weinstock, Caulfield South, AUSTRALIA;
 Remi Guibert, Mount Martha, AUSTRALIA;
 Maria C. Rodda, Mount Eliza, AUSTRALIA;
 Guy Eitzen, Wheelers Hill, AUSTRALIA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CIP of PCT/AU05/01667 10/28/2005

Foreign Applications

AUSTRALIA 2006902251 05/02/2006
 AUSTRALIA 2004906315 11/03/2004

If Required, Foreign Filing License Granted: 05/25/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is
US11/797,352

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

Incontinence management system and diaper

Preliminary Class

604

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under

37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/797,352	05/02/2007	Frederick Bergman	P71951US0

CONFIRMATION NO. 6338

FORMALITIES
LETTER

136
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC 20004

Date Mailed: 05/25/2007

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

*Filing Date Granted***Items Required To Avoid Abandonment:**

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
Applicant must submit \$ 300 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).
- The oath or declaration is missing. *A properly signed oath or declaration in compliance with 37 CFR 1.63, identifying the application by the above Application Number and Filing Date, is required.*
Note: If a petition under 37 CFR 1.47 is being filed, an oath or declaration in compliance with 37 CFR 1.63 signed by all available joint inventors, or if no inventor is available by a party with sufficient proprietary interest, is required.

The application is informal since it does not comply with the regulations for the reason(s) indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Replacement drawings in compliance with 37 CFR 1.84 and 37 CFR 1.121(d) are required. The drawings submitted are not acceptable because:
 - The drawings must be reasonably free from erasures and must be free from alterations, overwriting, interlineations, folds, and copy marks. See Figure(s) FIG. 5A-B.
 - Numbers, letters, and reference characters on the drawings must measure at least 0.32 cm (1/8 inch) in height. See Figure(s) 2-4.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to

exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

The applicant needs to satisfy supplemental fees problems indicated below.

The required item(s) identified below must be timely submitted to avoid abandonment:

- Additional claim fees of **\$3750** as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$4880** for a non-small entity

- **\$300** Statutory basic filing fee.
- **\$130** Surcharge.
- The application search fee has not been paid. Applicant must submit **\$500** to complete the search fee.
- The application examination fee has not been paid. Applicant must submit **\$200** to complete the examination fee for a non-small entity.
- Total additional claim fee(s) for this application is **\$3750**
 - **\$800** for 4 independent claims over 3.
 - **\$2950** for 59 total claims over 20.

Replies should be mailed to: Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
PART 3 - OFFICE COPY

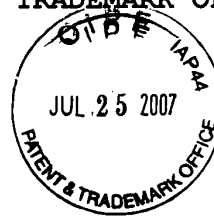
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Frederick BERGMAN et al.

Serial No.: 11/797,352

Filing Date: May 2, 2007

For: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER



**RESPONSE TO NOTICE TO FILE MISSING PARTS OF
NONPROVISIONAL APPLICATION UNDER 37 C.F.R. §1.53(b)**

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**Attention: APPLICATION BRANCH
MISSING PARTS OF APPLICATION**

Sir:

With respect to the above-identified patent application, the following are filed herewith in response to the Notice to File Missing Parts of Nonprovisional Application under 37 C.F.R. §1.53(b), mailed **May 25, 2007**, copy attached.

- X Declaration in compliance with 37 C.F.R. §1.63 with added page to Declaration (3 sheets in total).
- X Small Entity Declaration under 37 C.F.R. §§1.9 and 1.27.
- X Replacement drawings.
- X Certified copy of Australian Application No. **2004906315**, filed **November 3, 2004**, the priority of which is claimed under 35 U.S.C. §119.
- X Certified copy of Australian Application No. **2006902251**, filed **May 2, 2006**, the priority of which is claimed under 35 U.S.C. §119.
- X If a Petition for Extension of time is necessary and the Petition and/or the check is not enclosed, this will act as the Petition and applicant herewith petitions the Commissioner to extend the time for response and charge and fees necessary under 37 CFR 1.17 (a) - (d) to Deposit Account No. 06-1358. The Commissioner is also authorized to charge payment of any other additional fees associated with this communication or credit any overpayment to Deposit Account No. 06-1358.

Serial No.: 11/797,352

X Filing Fee, calculated as follows:

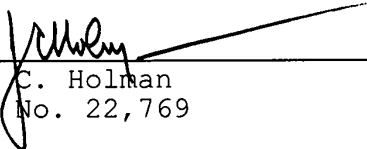
	<u>Small Entity</u>	<u>Large Entity</u>	
Basic Filing Fee	\$150 //	\$300	150.00
Utility Search Fee	\$250 //	\$500	250.00
Utility Examination Fee	\$100 //	\$200	100.00
Total Claims: <u>79</u> - 20 = <u>59</u>	(x \$25 =) //	(x \$50 =)	1475.00
Indep. Claims: <u>7</u> - 3 = <u>4</u>	(x \$100 =) //	(x \$200 =)	400.00
<u>X</u> Surcharge-Late Filing:		+ \$65 //	+ \$130 65.00
<u>X</u> Extension Fee under 37 CFR \$1.17			---.00
			+
		TOTAL FILING FEES	\$ 2440.00

A Credit Card Payment Form authorizing the amount of \$2440.00 is enclosed to cover the Filing Fee and late filing surcharge. The Commissioner is hereby authorized to debit or credit any fees set forth in §1.16 or §1.17 to Deposit Account No. 06-1358 as needed in order to effect proper filing of the application. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By

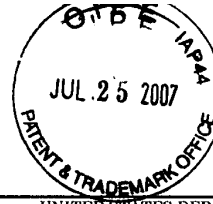

John C. Holman
Reg. No. 22,769

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666

Atty. Docket No.: P71951US0
Date: July 25, 2007
JCH/cmf



UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
11/797,352	05/02/2007	Frederick Bergman	P71951US0

CONFIRMATION NO. 6338

FORMALITIES
 LETTER

136
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC 20004

Date Mailed: 05/25/2007

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b) 07/26/2007 MAHHE1 00000167 11797352

Filing Date Granted

01 FC:2011	150.00 OP
02 FC:2111	250.00 OP
03 FC:2311	100.00 OP
04 FC:2222	1475.00 OP
05 FC:2221	400.00 OP
06 FC:2051	65.00 OP

Items Required To Avoid Abandonment:

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Applicant must submit \$ 300 to complete the basic filing fee for a non-small entity. If appropriate, applicant may make a written assertion of entitlement to small entity status and pay the small entity filing fee (37 CFR 1.27).
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- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.16(f) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

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 - **\$2950** for 59 total claims over 20.

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Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Office of Initial Patent Examination (571) 272-4000, or 1-800-PTO-9199
PART 2 - COPY TO BE RETURNED WITH RESPONSE



**DECLARATION
AND POWER OF ATTORNEY
U.S.A.**

ALL PATENTS, INCLUDING DESIGN
FOR APPLICATION BASED ON PCT; PARIS CONVENTION;
NON PRIORITY; OR PROVISIONAL APPLICATIONS

FOR ATTORNEYS' USE ONLY

ATTORNEYS' DOCKET NO.

P71951US0

As a below named inventor, I declare that my residence, post office address and citizenship are stated below next to my name, the information given herein is true, that I believe that I am the original, first and sole inventor (if only one name is listed at 201 below), or an original, first and joint inventor (if plural inventors are named below at 201-203, or on additional sheets attached hereto) of the subject matter which is claimed and for which patent is sought on the invention entitled:

INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

which is described and claimed in: ☐ PCT International Application No. _____ filed _____
☒ the specification in application Serial No. _____ filed **2 May 2007**
(if applicable) and amended on _____

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.
I hereby claim foreign priority benefits under Title 35, United States Code, §119 (a) (2) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

2006902251 (Number)	Australia (Country)	2 May 2006 (Day/Month/Year Filed)	<input checked="" type="checkbox"/> <input type="checkbox"/> Yes No
2004906315 (Number)	Australia (Country)	3 November 2004 (Day/Month/Year Filed)	<input checked="" type="checkbox"/> <input type="checkbox"/> Yes No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	<input type="checkbox"/> <input type="checkbox"/> Yes No

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

Application No. _____ Filing Date _____ Application No. _____ Filing Date _____

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

PCT/AU2006/001667 **28 October 2006** **pending**
(Application Serial No.) (Filing Date) (Status: patented, pending, abandoned)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorneys (Registration No.) to prosecute this application, receive and act on instructions from my agent, and transact all business in the Patent and Trademark Office connected therewith: HARVEY B. JACOBSON, JR. (20,851); JOHN CLARKE HOLMAN (22,769); ALLEN S. MELSER (27,216); MICHAEL R. SLOBASKY (28,421); JONATHAN L. SCHERER (28,851); WILLIAM E. PLAYER (31,409); N. WHITNEY WILSON (38,661); SUZIN C. BAILEY (40,495); and NATHANIEL A. HUMPHRIES (22,772)

<p>SEND CORRESPONDENCE TO: CUSTOMER NO. 00136 or JACOBSON HOLMAN PROFESSIONAL LIMITED LIABILITY COMPANY 400 SEVENTH STREET, N.W. WASHINGTON, D.C. 20004</p>	<p>DIRECT TELEPHONE CALLS TO: (please use Attorney's Docket No.) (202) 630-6666 JACOBSON HOLMAN PROFESSIONAL LIMITED LIABILITY COMPANY</p>
--	--

*Inventor(s) name must include at least one unabbreviated first or middle name.

201	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY	ZIP CODE
202	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY	ZIP CODE
203	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY	ZIP CODE

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
DATE 11th July 2007	DATE 23 May 2007	DATE 23 May 2007

☒ Additional inventors are named on separately numbered sheets attached hereto.

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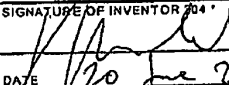
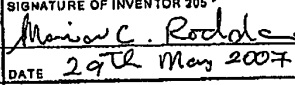
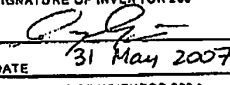
**Inventor is deceased, please see added page to combined Declaration and Power of Attorney

JACOBSON HOLMAN PLLC
ADDITIONAL INVENTORS

* Inventor(s) name must include at least one unabbreviated first or middle name.

204	FULL NAME * OF INVENTOR	FAMILY NAME GUIBERT	GIVEN NAME Reoni	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY Mount Martha VIC	STATE OR FOREIGN COUNTRY Australia	COUNTRY OF CITIZENSHIP Australia
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 27 Ellerslie Road	CITY Mount Martha VIC	STATE OR COUNTRY Australia
			ZIP CODE 3934	
205	FULL NAME * OF INVENTOR	FAMILY NAME RODDA	GIVEN NAME Marla	MIDDLE NAME C.
	RESIDENCE & CITIZENSHIP	CITY Mount Eliza VIC	STATE OR FOREIGN COUNTRY Australia	COUNTRY OF CITIZENSHIP Australia
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 88 Koornalla Crescent	CITY Mount Eliza VIC	STATE OR COUNTRY Australia
			ZIP CODE 3130	
206	FULL NAME * OF INVENTOR	FAMILY NAME EITZEN	GIVEN NAME Guy	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY Wheeler Hill VIC	STATE OR FOREIGN COUNTRY Australia	COUNTRY OF CITIZENSHIP Australia
	POST OFFICE ADDRESS	POST OFFICE ADDRESS 4 Wilton Crescent	CITY Wheeler Hill VIC	STATE OR COUNTRY Australia
			ZIP CODE 3160	
207	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY
			ZIP CODE	
208	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY
			ZIP CODE	
209	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY
			ZIP CODE	
210	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY
			ZIP CODE	
211	FULL NAME * OF INVENTOR	FAMILY NAME	GIVEN NAME	MIDDLE NAME
	RESIDENCE & CITIZENSHIP	CITY	STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS	POST OFFICE ADDRESS	CITY	STATE OR COUNTRY
			ZIP CODE	

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are to be true, and further that these statements were made with the knowledge that without false statements and the like so made are punishable by fine or imprisonment or both, under section 1001 of Title 18 of the United States Code; and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 204 *	SIGNATURE OF INVENTOR 205 *	SIGNATURE OF INVENTOR 206 *
		
DATE 20 May 2007	DATE 29th May 2007	DATE 31 May 2007
SIGNATURE OF INVENTOR 207 *	SIGNATURE OF INVENTOR 208 *	SIGNATURE OF INVENTOR 209 *
DATE	DATE	DATE
SIGNATURE OF INVENTOR 210 *	SIGNATURE OF INVENTOR 211 *	
DATE	DATE	

□ Additional Inventors are named on separately numbered sheets attached hereto.
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ADDED PAGE TO COMBINED DECLARATION AND POWER OF
ATTORNEY FOR SIGNING BY ADMINISTRATOR(TRIX),
EXECUTOR(TRIX) OR LEGAL REPRESENTATIVE ON BEHALF OF
DECEASED OR INCAPACITATED INVENTOR (37 CFR 1.42 AND 1.43)

ARI BERGMAN

(type or print name(s) of administrator(trix), executor(trix), legal representative or all heirs)

herby declare that I am a citizen of AUSTRALIA

residing at 5 EDINBURGH STREET, CAULFIELD, VIC
3162 AUSTRALIA

and that I am executing and signing the declaration to which this is attached as (check
one):

- ☐ the administrator(trix) of
☐ executor(trix) of the last will and testament of
☒ legal representative (or heirs) of

FREDERICK BERGMAN

Full name of (first, second etc.) deceased or incapacitated inventor

AUSTRALIA

Country of citizenship of deceased or incapacitated inventor

72 SEMMOUR ROAD ELSTERNWICK 3185

Residence of deceased or incapacitated inventor

AS ABOVE

Post Office Address of deceased or incapacitated inventor

NOTE: The name of the first, second etc. deceased or incapacitated inventor should preferably also be filled
in at the appropriate prior space of the declaration adding the words "deceased-completed on added
page" or "incapacitated-completed on added page."

That, upon information and belief, I aver those facts which the inventor is required to
state.

Date: 11th July 2007

A. Bergman
(Signature of administrator(trix), executor(trix)
legal representative (or all heirs))



Law Offices of
JACOBSON HOLMAN
 PROFESSIONAL LIMITED LIABILITY COMPANY
 THE JENIFER BUILDING
 400 SEVENTH STREET, N.W.
 WASHINGTON, DC 20004

Attny's Docket No. P71951US0

SMALL ENTITY DECLARATION
 [37 CFR 1.27(a)(1)-(3)]

Each undersigned declares that:

(1) ☐ the application attached hereto.

(2) ☒ U.S. Application Serial No. _____, filed 2 May 2007

(3) ☐ U.S. Patent No. _____, Issued _____

is entitled to the benefits of "small entity" status for paying reduced fees under 35 USC 41(a) and (b) to the Patent and Trademark Office by virtue of the following:

(4) ☐ Each undersigned declares that he/she qualifies as an independent inventor, or would qualify had he/she made the invention, as defined in 37 CFR 1.27(a)(1).

(5) ☒ The undersigned declares that he/she is an official empowered to act on behalf of the concern identified below; that this concern qualifies as a small business concern as defined in 37 CFR 1.27(a)(2); that exclusive rights to the invention have been conveyed to and remain with the small business concern, or if the rights are not exclusive, that all other rights belong to small entities as defined in 37 CFR 1.27(a).

(6) ☐ The undersigned declares that he/she is an official empowered to act on behalf of the organization identified below; that this organization qualifies as a nonprofit organization as defined in

(a) ☐ 37 CFR 1.27(a)(3)(i) and (ii)(A)

(b) ☐ 37 CFR 1.27(a)(3)(i) and (ii)(B)

(c) ☐ 37 CFR 1.27(a)(3)(i) and (ii)(C) State law of _____

(d) ☐ 37 CFR 1.27(a)(3)(i) and (ii)(D); and

that exclusive rights to the invention have been conveyed to and remain with the organization, or if the rights are not exclusive, that all other rights belong to organizations as defined in 37 CFR 1.27(a).

(7) Each person, concern or organization to which I/we have assigned, granted, conveyed or licensed, or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

(a) ☒ no such person, concern or organization

(b) ☐ persons, concerns or organization listed below

[a separate declaration is required from each named person, concern or organization having rights to this invention averring to their status as "small entities."]

Full Name _____

Address _____

☐ Individual

☐ Small Business Concern

☐ Nonprofit Organization

I/we acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement of small entity prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I/we hereby declare all statements made herein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application, any patent issued thereon, or any patent to which this declaration is directed.

(8)	_____	_____	_____
	Typed Name of Inventor	Signature	Date
	_____	_____	_____
	Typed Name of Inventor	Signature	Date
	_____	_____	_____
	Typed Name of Inventor	Signature	Date
	_____	_____	_____
	Typed Name of Inventor	Signature	Date

(9) FRED BERGMAN HEALTHCARE PTY. LTD
 Name of Small Business Concern or Nonprofit Organization
ARI BERGMAN By 11th July 2007
 Typed Name Signature Date
DIRECTOR
 Title of Signatory

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JA0103

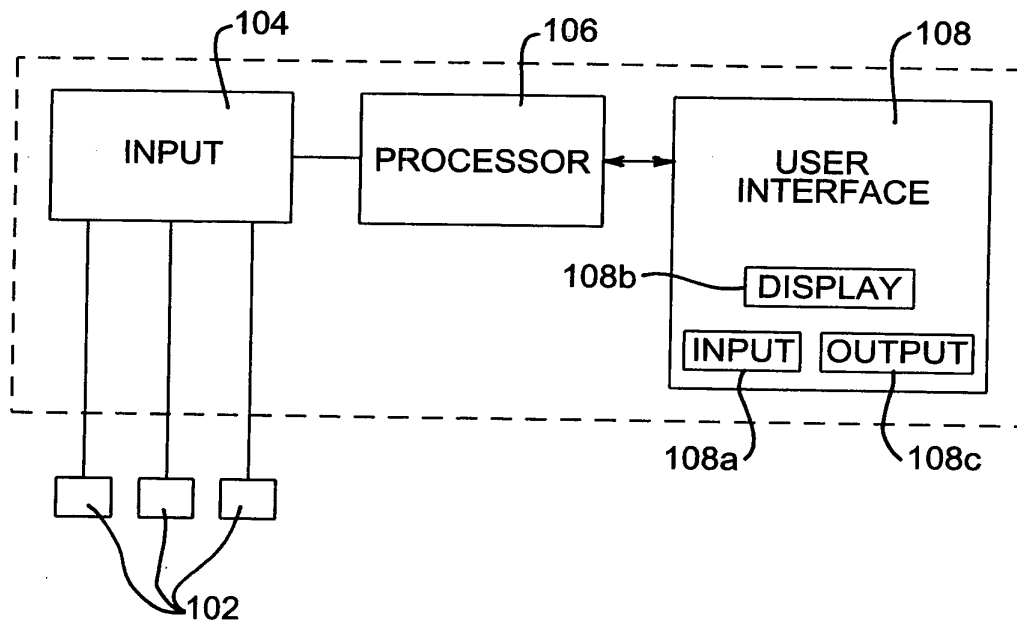


FIG 1

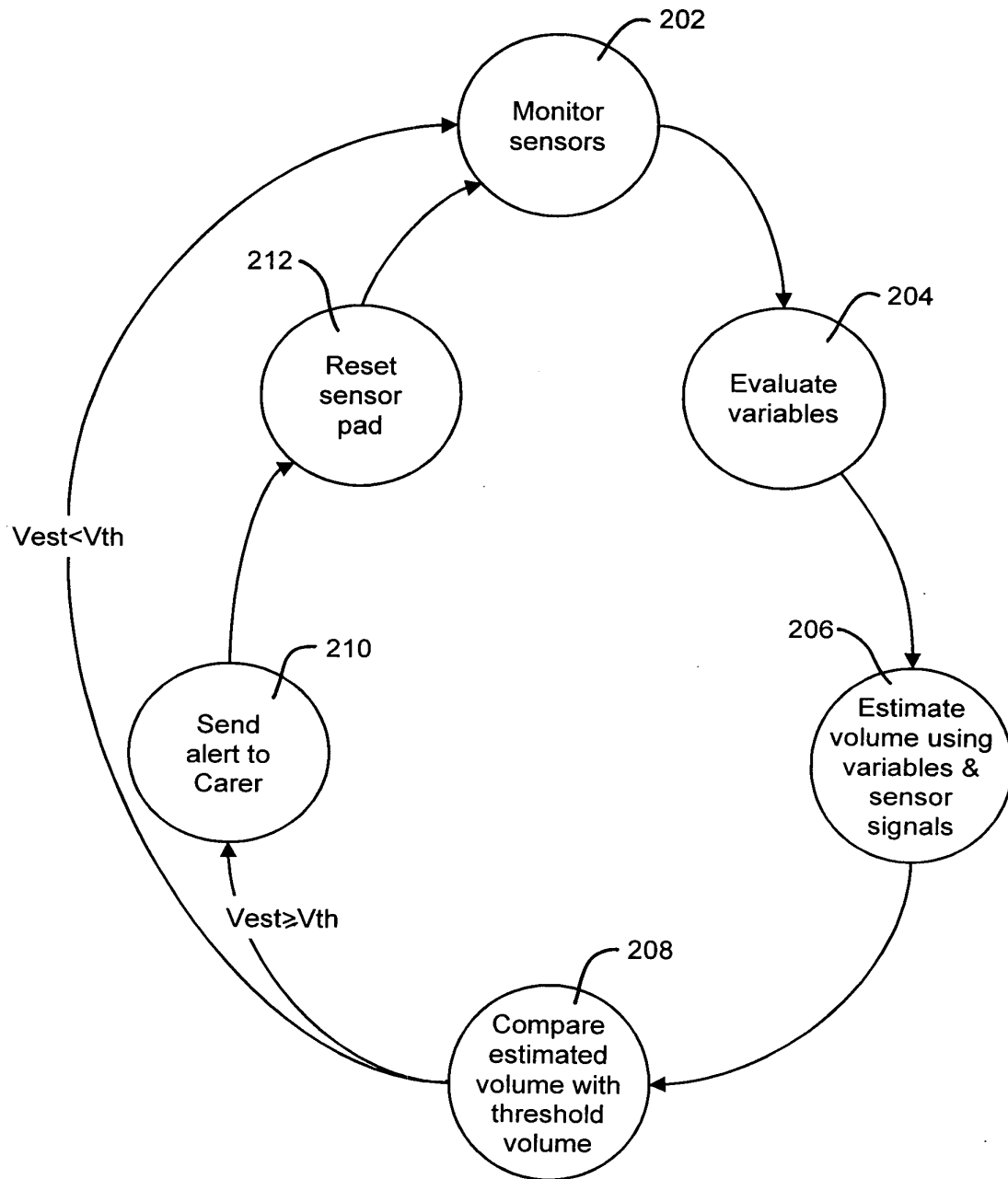


FIG 2

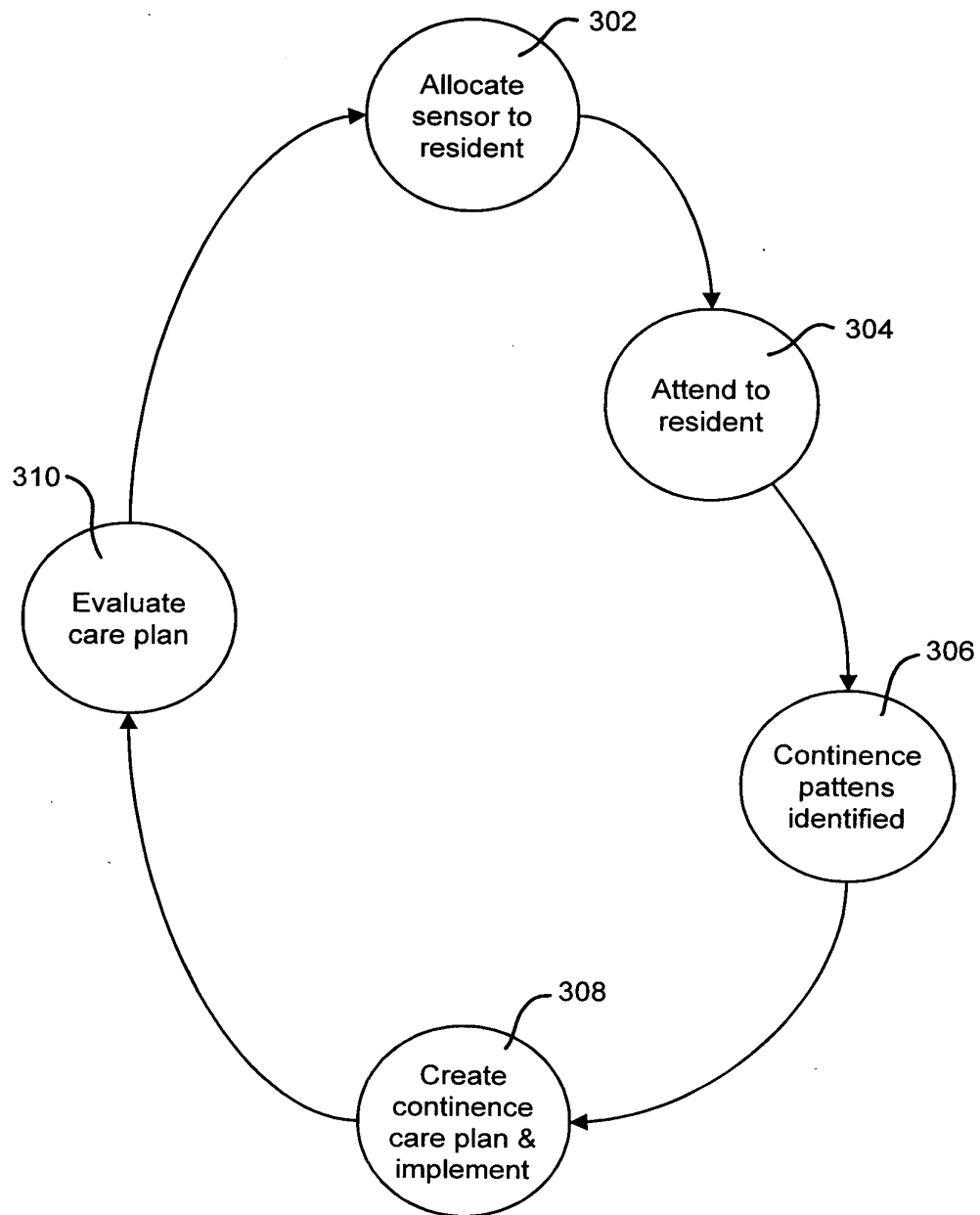


FIG 3

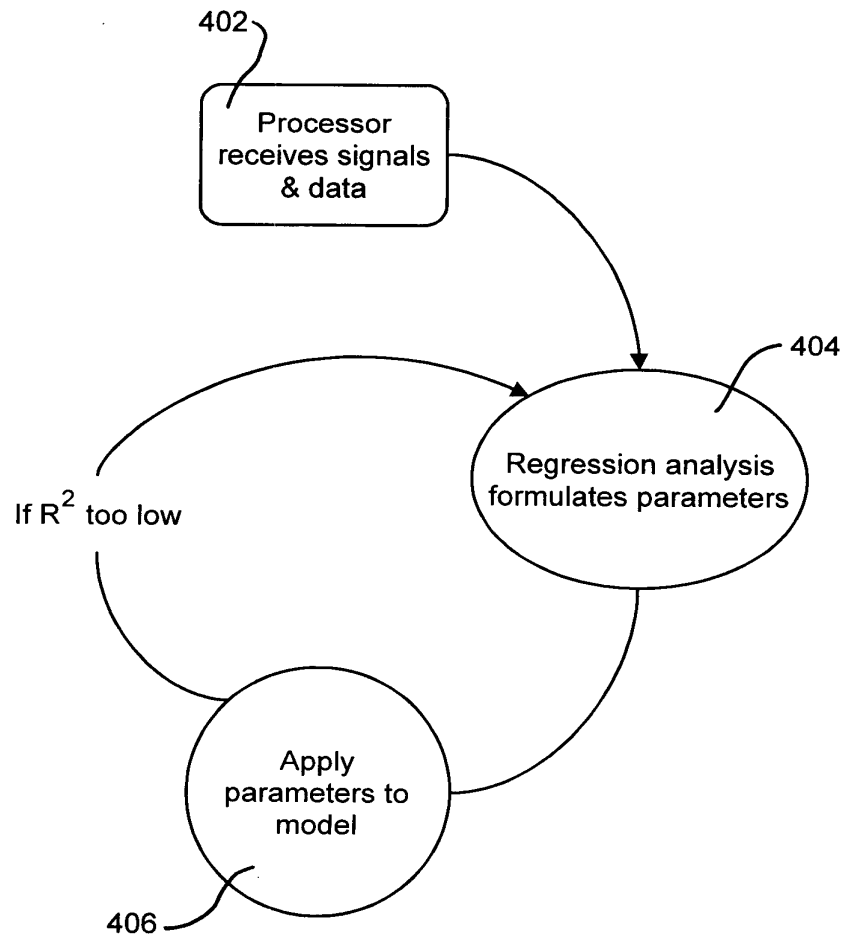


FIG 4

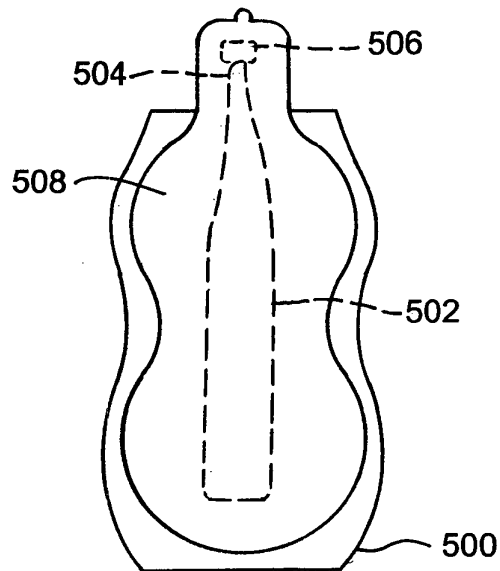


FIG 5a

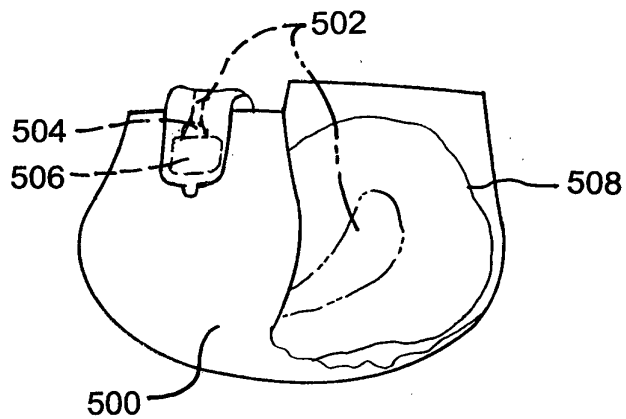


FIG 5b

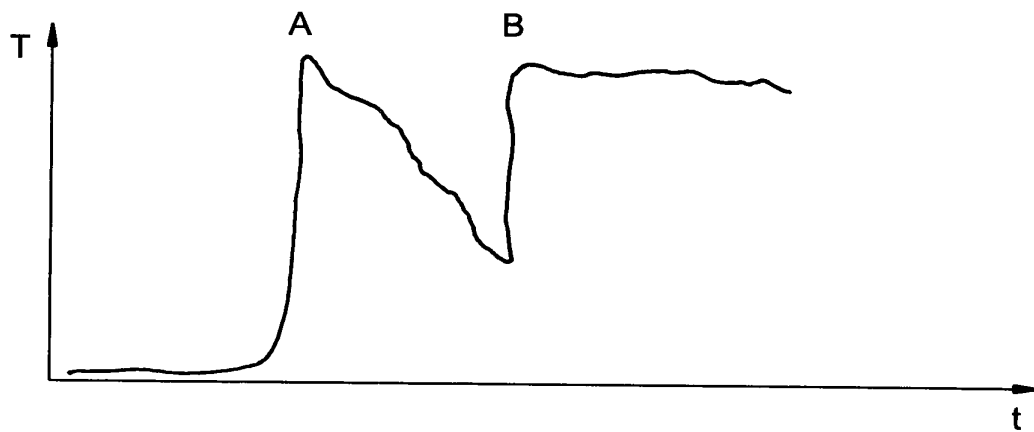


FIG 6

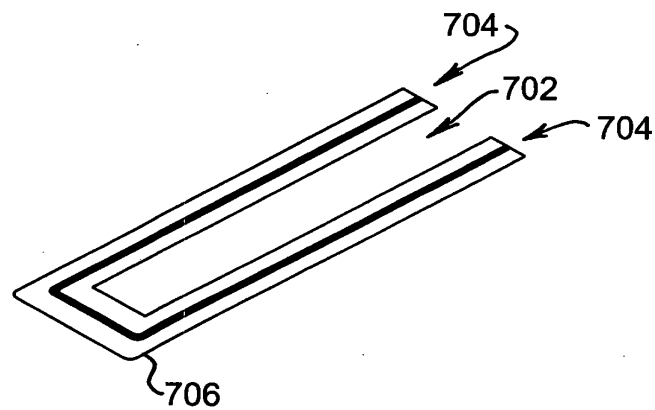


FIG 7

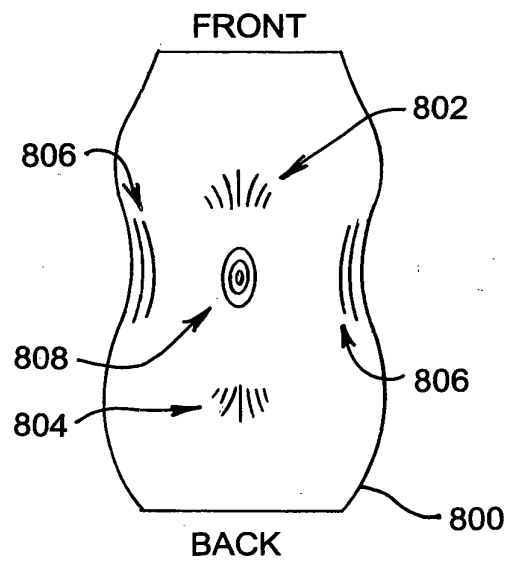


FIG 8

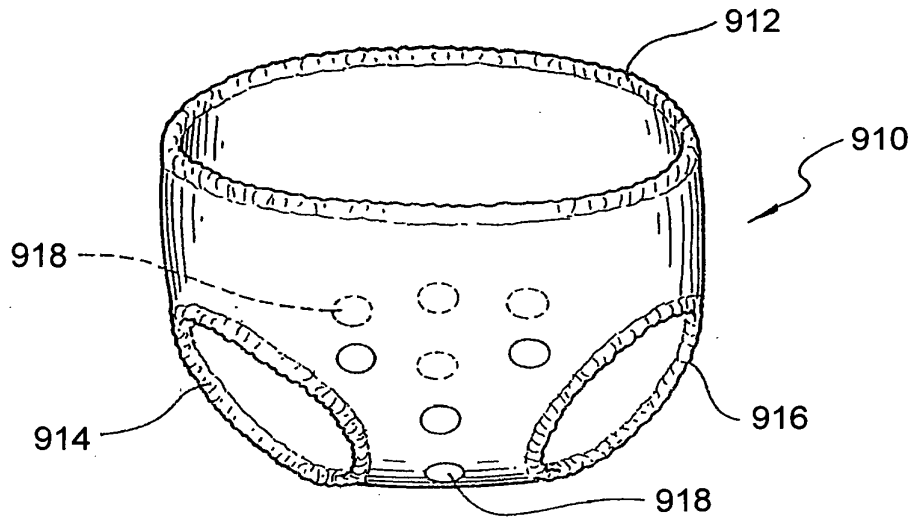


FIG 9

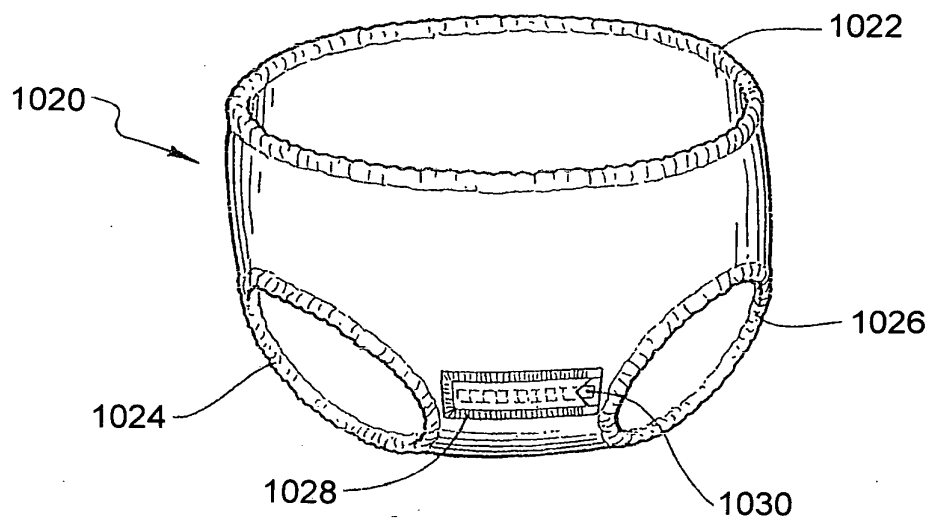
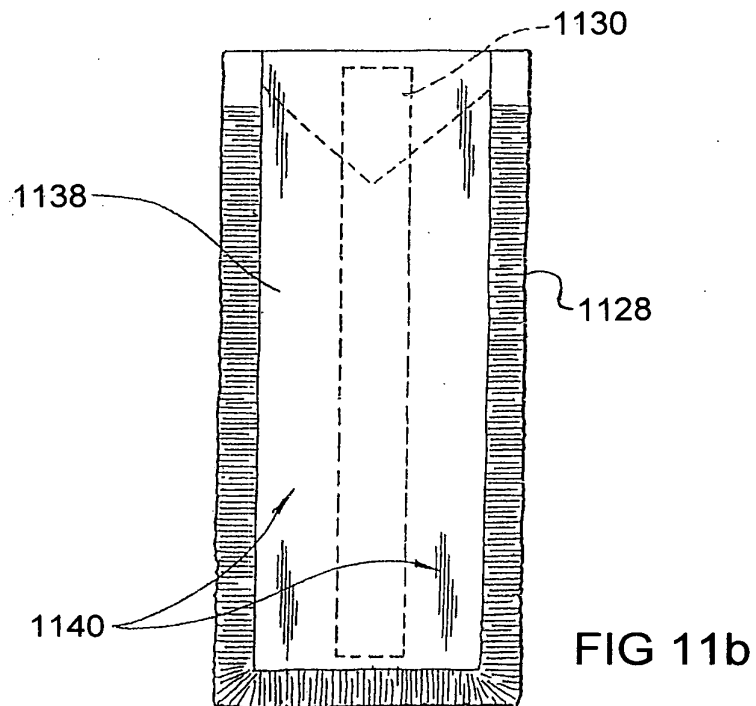
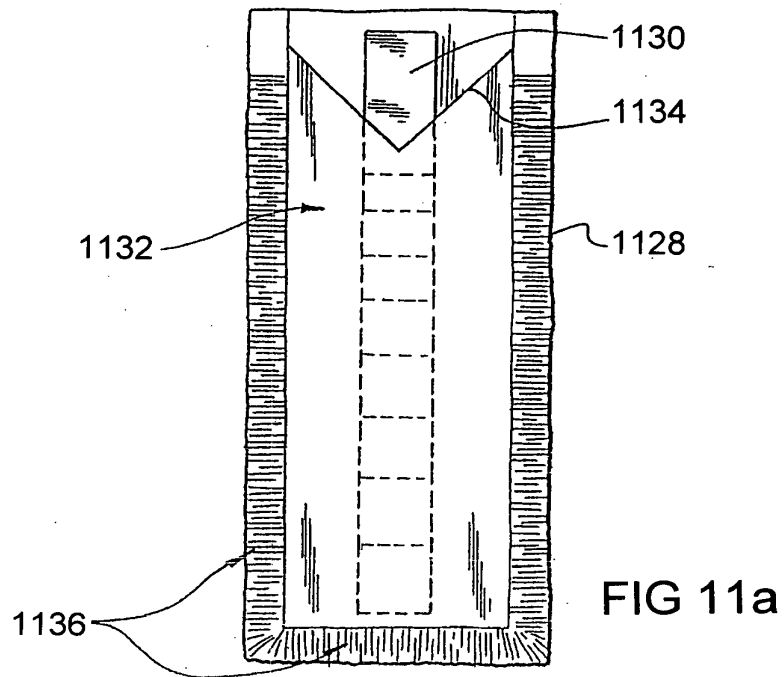


FIG 10



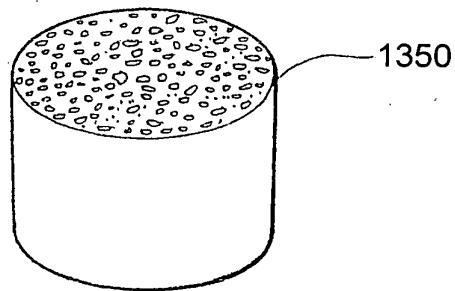
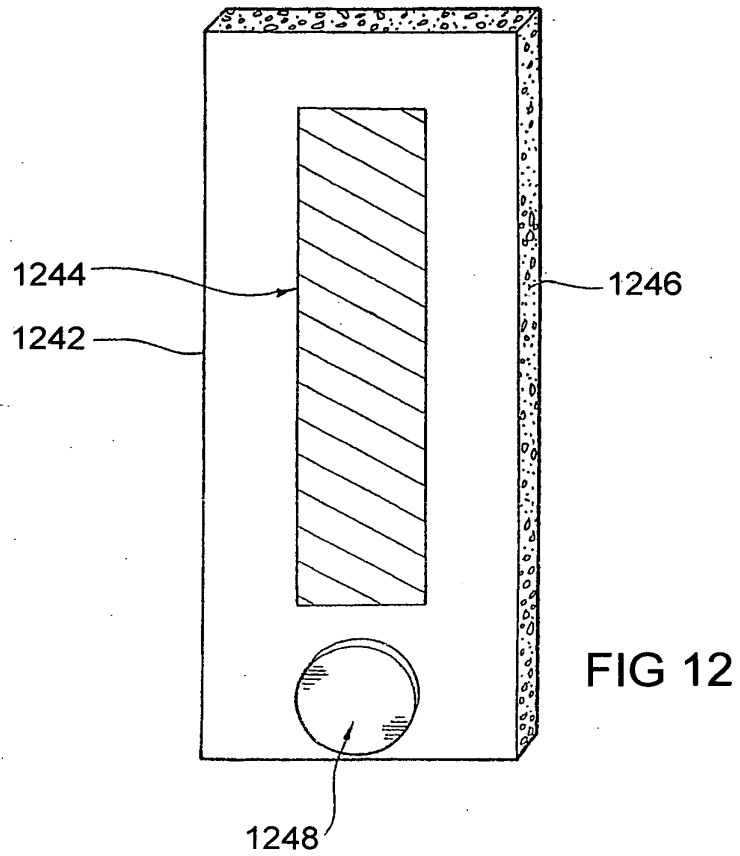


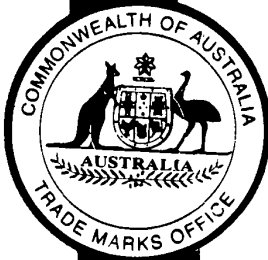
FIG 13



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I, JANENE BRYDE, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2004906315 for a patent by C. & M. INVESTMENT NOMINEES PTY. LTD. as filed on 03 November 2004.



WITNESS my hand this
Seventh day of June 2007

A handwritten signature in cursive script, reading 'J K Bryde'.

JANENE BRYDE
MANAGER
EXAMINATION SUPPORT AND SALES

1

P/00/009
Regulation 3.2

2004906315 03 Nov 2004

COMMONWEALTH OF AUSTRALIA
Patents Act 1990

ORIGINAL

PROVISIONAL SPECIFICATION

Invention Title: INCONTINENCE MANAGEMENT SYSTEM

The invention is described in the following statement:

JA0116

This invention relates to a system for managing incontinence, to elements of such a system, and to associated detection, monitoring and treatment systems, methods and apparatus.

Incontinence, in the context of this specification, includes urinary and faecal incontinence, and management of such incontinence is to be seen in the context of persons located in hospitals, nursing homes, aged care centres, geriatric institutions, private homes, gardens and the like.

The aforementioned incontinence, when unchecked, may result in the person suffering from the condition experiencing discomfort or at least embarrassment, and in the existence of unpleasant odours and environment for others in the vicinity of the person. In addition, health regulations or protocols may prescribe a maximum period, such as 15 minutes, for which a patient may be left in a wet state caused by incontinence. In the past, to comply with such requirements, it has been necessary for nursing staff to manually check each patient at least once during the prescribed period. Apart from the unpleasantness experienced by nursing staff in carrying out such manual checks, such a regimen may place a severe strain on staff resources, and may constitute an interruption to patients' rest and sleep.

In WO 96/14813 there is described an incontinence management system in which remote sensors are associated with patients, the sensors being responsive to urinary and/or faecal incontinence, and to generate and send signals consistent with such incontinence by radio to a monitor, which monitor receives and records the signals. Such a system enables data to be collected for each patient, to enable any regularity or pattern of incontinence to be determined. Staffing assistance for a patient is also able to be obtained through the system.

US-A-5,291,181 relates to a wet bed alarm and temperature monitoring system.

In addition to an incontinence sensor, the system has a temperature sensor.

There is disclosure of a remote transmitter and receiver unit for use in the system.

US-A-5,903,222 describes a garment diaper detector utilising a capacitive sensor.

Also disclosed are multiple wetness detectors to monitor a plurality of garments, in a nursing home or hospital, and the transmission of a signal indicating wetness to

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a central monitoring station, which may be equipped with a modem which communicates the addresses of wet garments to pagers worn by carers.

Documents published since the aforementioned prior art seem to suggest that there has not been much of an advance in incontinence management systems.

5 WO 02/052302 discloses a radio frequency resonant circuit sensing device for the detection of fluid levels, empty containers, and leak of fluids from containers and bodies containing the fluids, in the monitoring of the collection of drain fluid from a person or the leak of fluid from a person suffering from urinary and/or faecal incontinence.

10 WO 02/078513 describes a patient fluid discharge/position monitoring apparatus and method including an article configured to be worn by a patient, the article having absorbent material and a RF tag adjacent the material. The RF tag is excited by an excitation signal and the response of the RF tag is detected. A first detected response occurs when the absorbent material has no fluid therein, and a

15 second detected response occurs when the material has fluid therein. The detected response is compared to a predetermined response.

Other recent prior art documents relate merely to the treatment of incontinence: US-A-6,110,099, US 2002/0142033 A1, and US 2001/0005728 A1 and related documents. WO 98/12997 discloses a basic pad for detecting *enuresis nocturna*,

20 which pad has a sensor consisting of a conductor printed on non-woven fabric. The pad is limited to the provision of an alarm when *enuresis nocturna* occurs.

It is clear that there is a need for a more sophisticated incontinence management system.

It is an object to provide an incontinence management system which is an

25 improvement over the prior art, or at least provides an alternative thereto.

The invention may provide, in a broad aspect, an incontinence management system or a system for the management of other exudates from the body of a person, characterised by an article adapted to be worn by the person, sensing means associated with said article and adapted to sense a condition, and

transmitting means adapted to transmit a signal generated by said sensing means to a location.

Preferably, said system also includes means for processing said signal.

Preferably, said sensing means is a plurality of sensors, arranged spatially in said article.

Said special arrangement includes the spacing of sensors at different thicknesses in material forming at least a part of said article.

The invention may also provide, in a broad aspect, a diaper to be worn by a person, for use in an incontinence management system or a system for the management of exudates from the body of a person, said diaper including a sleeve for the insertion of a diagnostic strip.

Preferably, said diaper is designed to direct fluids excreted by said person, to said sleeve.

The invention may further provide, in a broad aspect, a pad for use with a diaper, said pad being associated with transmitting means for transmitting signals representative of an aspect of fluids absorbed by said pad to a remote location.

Preferably, said pad includes a chamber for collection of said fluids.

Preferably, said chamber is removable.

Embodiments of the invention will be described in detail hereinafter, with reference to the accompanying drawings, in which:-

Fig. 1 is a diagrammatic perspective view of one embodiment of a diaper in accordance with the present invention;

Fig. 2 is a diagrammatic perspective view of a second embodiment of a diaper in accordance with the present invention;

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Fig. 3 is a front elevation of an embodiment of a sleeve for a diagnostic strip;

Fig. 4 is a rear elevation of an embodiment of a sleeve for a diagnostic strip;

Fig. 5 is a diagrammatic perspective view of a pad for use in an infant's diaper;
and

- 5 Fig. 6 is a diagrammatic perspective view of an alternative pad for use in an infant's diaper.

As well as the urinary and faecal incontinence referred to in the introduction to this specification, the present invention is intended to relate to the management, monitoring and treatment of the production of other bodily fluids and exudates from
10 the body of a patient or resident. Such bodily fluids may include cerebro-spinal fluid (CSF), peritoneal fluid, synovial fluid from joints and bursae around joints, and material discharged from wounds.

As has been described in the preamble to this specification, developments in incontinence management systems have largely been restricted to systems in
15 which the status of a patient suffering from urinary, faecal or other incontinence is remotely monitored to ensure compliance with protocols and patient comfort. The present invention, and embodiments thereof, contemplates the broadening of such systems to provide for diagnosis and treatment of conditions which result in incontinence.

- 20 An extensive list of clinically relevant medical conditions may be recognised or suspected by the detection of a number of metabolites, chemicals and ions, as well as other substances and cells of different types, in urine. Such materials as nitrites, amino acids, Beta-2 microglobulin, such measurements as pH, osmolality, white cell count, protein, specific gravity, and such conditions as multiple myeloma
25 and haematuria, may be detected by testing urine from a patient.

The system of the present invention has as its core a diaper to be worn by the patient, which diaper has features which enable it to monitor incontinence,

particularly urinary incontinence, by, for example, collecting data from the patient wearing the diaper, and transmitting it to a location where such data may be processed. The diaper may also include features which enable samples of, for example, urine, to be withdrawn *in situ* from such a diaper, for testing.

- 5 Fig. 1 shows a diaper 10 which is adapted to be worn by a patient (not shown). Preferably, the diaper 10 is disposable and/or re-usable, and preferably has an elasticised waistband 12 and elasticised upper thigh bands 14, 16. The diaper 10 is intended to permit the estimation of the volume of urine flowing from the patient in real time. This is effected by the placing of one or more moisture (wetness) sensors 18 at different locations in the diaper 10. The sensors 18 form part of a radio transmitting and data capturing arrangement (not shown), operated by special software.

- 15 Preferably, the sensors 18 are constituted by conductive inks, and will detect the presence of moisture. These conductive inks, which are preferably special conductive inks of various formulations, are connected to the aforementioned arrangement, which may be a purpose designed continence management system which captures the data captured by the sensors 18, which data is recorded via radio transmission to hardware running a computer software program. Some of the data may also be transmitted to nursing staff or a nursing station responsible for the management of the incontinence episode in an appropriate manner for the patient or resident in question.

- 25 The conductive inks used in the sensors 18 are preferably based on low-cost materials such as carbon, formulated on the carbon content of different concentrations and composition, to achieve the most appropriate sensitivity for moisture detection. Current conductive units are silver-based, and accordingly are too expensive for use in a disposable diaper.

- 30 The choice of carbon or a similar inert substance will reduce the likelihood of interference with chemical markers, which may be incorporated into the sensors 18, for the detection of clinically relevant substances of the type referred to earlier in this specification. Information captured by the chemical markers is transmitted using radio or the like technology, and processed by specially designed software,

to be used for improved management of clinical conditions of residents and patients by medical or nursing staff.

Preferably, the conductive ink will be such that rapid drying or curing will be achieved to enable manufacture of disposable diapers 10 to be carried out at rates
5 consistent with the production of existing and future diapers, presently in the order of 400 diapers per second. The manufacturing process may be carried out using ultraviolet light in a manner similar to that used in rapid curing of dental materials for various dental procedures such as dental fillings.

In a preferred arrangement, the volume of urine passed by the resident or patient,
10 preferably in a unit of time, will be established using a mathematical model computed by using such factors as the distance between sensors 18, the rate of transfer of moisture between sensors 18, and the absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres. The information from the sensors 18 is transmitted using
15 existing radio technology, and the data is processed using specially designed software running the aforementioned mathematical model.

The sensors 18 incorporate diagnostic qualities, which differ from the arrangement of Fig. 2, to be described hereinafter, because the system of Fig. 1 does not use blood-derived components.

20 Turning now to Fig. 2, that figure shows a diaper or the like 20 which may fundamentally be similar to the diaper 10 of Fig. 1, and which is adapted to be worn by a patient or resident suffering from some form of incontinence. Preferably, the diaper 20 is disposable and/or re-usable, and preferably has an elasticised waistband 22 and elasticised upper thigh bands 24, 26.

25 The diaper 20 has a sleeve 28 located preferably in the area of the diaper 20 close to the pubic area of the patient or resident. The sleeve 28 is intended to house a diagnostic strip or the like 30. Such diagnostic strips 30 may be of the Multistix/Combistix type or similar to other strips which are able to detect relevant substances in urine, for example blood, sugar, nitrites, leucocytes, urea, specific
30 gravity, protein, and other substances. As some of the chemical sensors on the

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strips 30 use and are derived from blood products, the sleeve 28 will protect the skin of the wearer from such blood derived products and thus accidental infection with hepatitis B, hepatitis C or HIV.

It is considered that as the information to be obtained from the diagnostic strips 30 may need to be obtained within certain time frames, the sleeve 28 will need to allow for a sufficient volume of urine to be captured so that the urine may make contact with the strip 30, and for radio transmission of data to take place within the required time frame.

Figs. 3 and 4 show front and rear views of an exemplary sleeve 28 for a diagnostic strip 30. The sleeve 28 is secured to diaper 20 as will be described hereinafter, and is designed and constructed of materials which will attract and capture urine from the patient or resident. This will expose the chemical sensors on the strip 30 to the collected urine.

The front 32 of the sleeve 28 may be provided with a V-shaped notch 34 for ease of insertion of a diagnostic strip 30. Pores and channels 36 may be provided to facilitate the drawing in of the urine to the interior of the sleeve 28, effectively "sucking up" the urine. The rear 38 of the sleeve 28 may be provided with adhesive material 40 for attaching the sleeve 28 to the diaper 20 or pad, in much the same manner as used in feminine hygiene products.

We have, earlier in this specification, referred to clinically relevant medical conditions which may be recognised in urine samples. A sleeve 28 according to the present invention will allow urine to be captured in sufficient volume to permit the detection of relevant clinical substances. The interpretation of the results of such detection are preferably based upon a recalibration of what may be regarded as normal or abnormal, compared to existing "dipsticks", which have established normal and abnormal values for interpretation. This re-standardising may be required to take account of any alteration which may occur in the components in the urine samples, as a result of the present invention. For example, diaper fibres may trap some white blood cells, so that a new "normal value" may be needed to be established to cater for such a possibility. As a consequence, a new lower value for the number of leucocytes in a sample may be required.

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Another example relates to the test for the albumen:creatinine ratio in a spot urine sample. A level of 0.7 mg/mmol corresponding to a urinary excretion rate of more than 5 mgm/min would indicate a high-risk (in cardiovascular terms) patient requiring aggressive treatment. This marker of arterial damage may be considered with raised cholesterol and hypertension as a serious risk factor for cardiovascular disease. Such values would be revised if necessary for the purposes of the present invention.

The sleeve operates as follows. Urine is drawn into the sleeve 28 via capillary action, osmosis and semipermeable membrane processes, thereby bringing the urine into contact with a diagnostic strip 30, which may be a proprietary strip such as marketed under the Bayer and Roche brands, to enable the "reading" to take place in a timely fashion. The carer or nurse will have been alerted to the availability of the urine sample through the radio-based system and software-based system described earlier in this specification.

Patients or residents may be required to take standard known quantities of substances such as creatinine to carry out reliable, accurate tests which the incontinence management system is able to interpret reliably. Such ingested substances may be excreted in an unmetabolised form, for example, as creatinine asparagine, or may be actively metabolised and measured as a metabolite in the urine.

The embodiment of Figs. 3 and 4 of the present invention makes possible the interpretations of findings in near real time, as the requirement of testing fresh, recently passed, urine is essential for the most accurate interpretations to take place.

In Fig. 5 there is shown a pad 42 which preferably is adapted to be attached to a diaper (not shown) of a neonate, baby or a child, more preferably by adhesive means such as 44. The pad 42 itself is preferably formed from an absorbent material 46 such as a sponge or sponge-like material, to take up urine excreted by the baby. The pad 42 may also preferably be fitted with a transmitter 48 for transmitting data to the system(s) described previously in this specification. One example of such a signal would be a signal representative of the fact that voiding

had taken place. This may be accomplished by linking the transmitter 48 with a wetness sensor (not shown).

Currently, there are three existing sample collection methods, where the collection samples are carried out by "catch" techniques, adhesive collection bags, or suprapubic bladder puncture. There are also "time interval" tests, such as 1-hour and 2-hour tests to establish levels of incontinence during the stated time intervals, in which conventional pads are simply weighed to determine the volume of urine. These are termed "pad tests".

The pad 42 shown in Fig. 5 is much more sophisticated. It preferably comes in three versions. The first version would be a "wetness only" signalling pad, where a parent or nurse would be alerted in real time of passage of urine, would collect the pad and place it in a suitable container to be sent promptly to the microbiology and pathology lab for testing, or would draw up the urine via a syringe for placement in a container, with the container being sent to the lab.

The second type involves the pad 42 having a collecting chamber (not shown) incorporated therein, into which urine has been drawn. This chamber is preferably removable, so that it may be removed when a predetermined amount of urine, or urine passed in a predetermined period of time has been passed, and sent to the microbial/pathology lab.

The third type of pad 42 would have a chamber such as that described in relation to the second type, but which would include diagnostic strips of the type and purpose described hereinbefore in relation to Figs. 2 to 4. The design of the collection chamber, sleeve or pocket will be such that it will collect urine for dipstick testing, for collection of samples to be transported for pathology/bacteriology testing, or *in situ* testing using the new sensors designed for the incontinence management system.

The collection chamber, sleeve or pocket will be designed in conjunction with the diaper to which it is attached, which diaper draws and feeds the urine into the chamber, to maximise the volume of urine collected, when only small voids have occurred.

Alternatively, urine may be expunged from a urine-soaked pad 42 via a special container which may expel urine by the use of a plunger (not shown), which may be compared to the plunger in a coffee plunger, which is able to force urine into a sealed compartment (not shown), separate from the pad 42.

- 5 The pad 42 may have capillary channels (not shown, but preferably similar to channels 36 of Fig. 3, to draw the urine towards the collection chamber. The pad 42 and/or diaper containing the pad 42 may also preferably use materials designed for osmosis, capillary action or other manner of providing directional flow of urine to assist in the transfer of the urine to a location where it is required.

- 10 Fig. 6 shows an alternative pad 50, which may be generally similar to pad 42 of Fig. 5, but which has a generally cylindrical shape.

Reference is now made to the extension of the present invention to other bodily fluids and exudates from the body of a person. In the case, for example, of serous and other exudates, a dressing for a wound are preferably provided such that

- 15 information about the wound may be relayed via sensors located on or in association with the dressing, which would otherwise be difficult to determined because conventional dressings or casts would be in the way.

It may also be the intention of the present invention to provide sensors of the dipstick and/or electronic type for dressings on wounds. Additional components, ions and chemical markers of bodily fluids or exudates from the body, may be detected *in situ* or via the sensors located on or in association with the sensors.

- 20 Presently, such body products are tested away from the patient in biochemical and bacteriological laboratories. The sensor-equipped dressings may also be used to inform nursing staff of ooze, and content.

- 25 Since modifications within the spirit and scope of the invention may readily be effected by persons skilled in the art, it is to be understood that the invention is not limited to the particular embodiment(s) described, by way of example, hereinabove.

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12

DATED this 2 November 2004

JOHN CHRISTIANSEN

Patent Attorney for the Applicant:

C. & M. INVESTMENT NOMINEES PTY. LTD.

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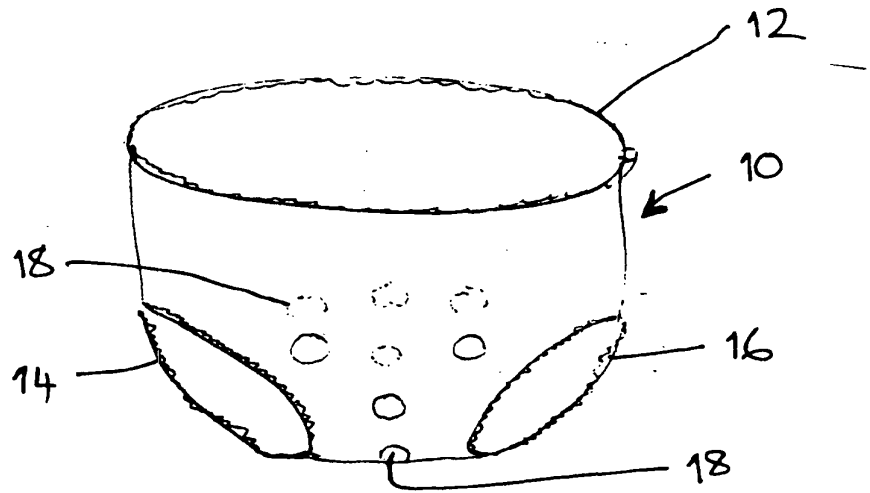


Fig. 1

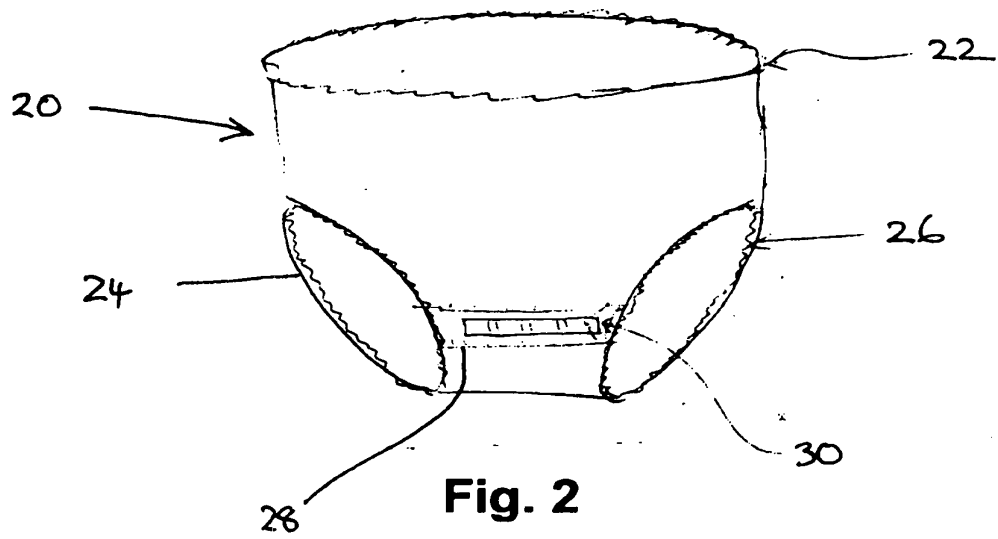


Fig. 2

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Fig. 3

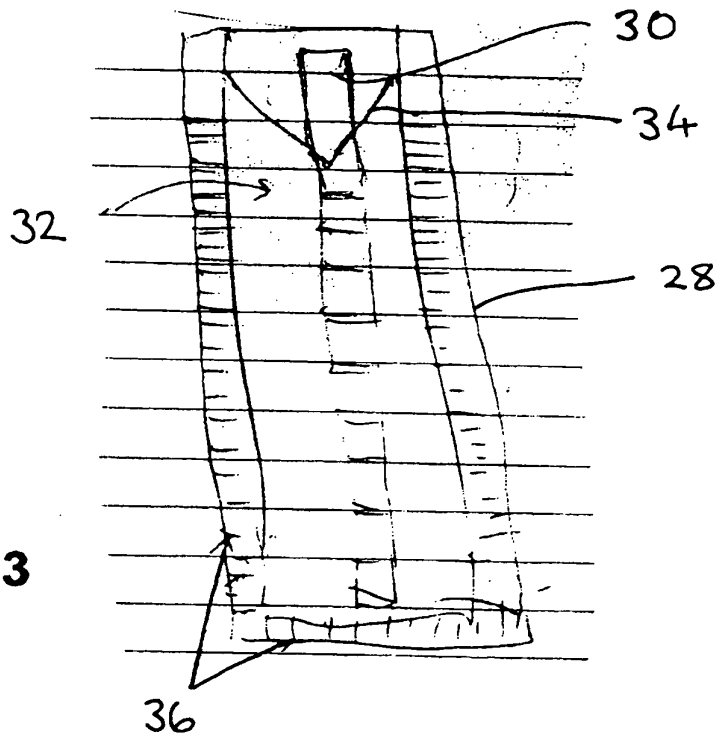
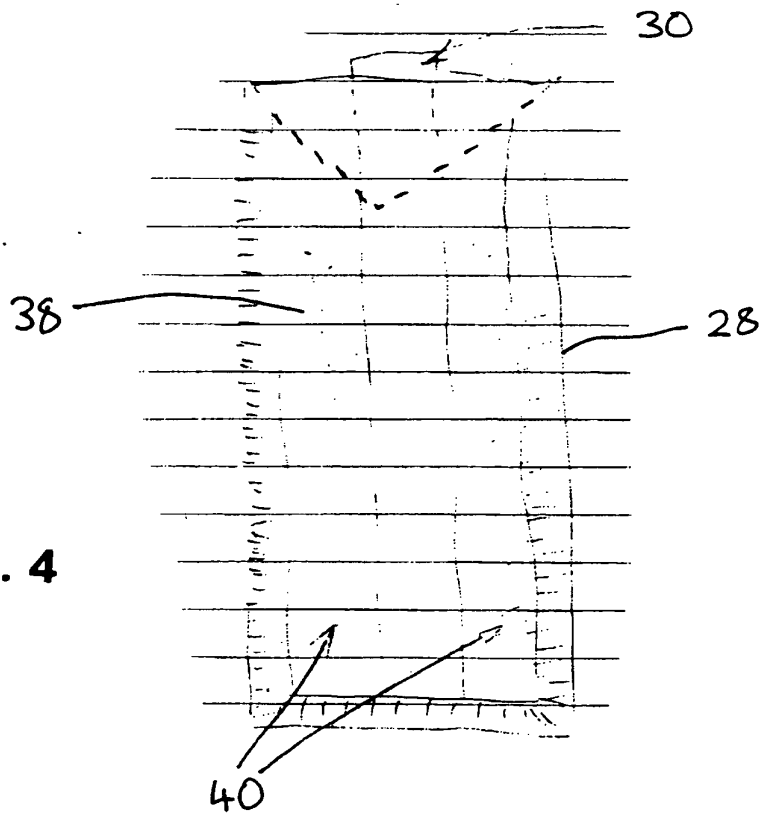


Fig. 4



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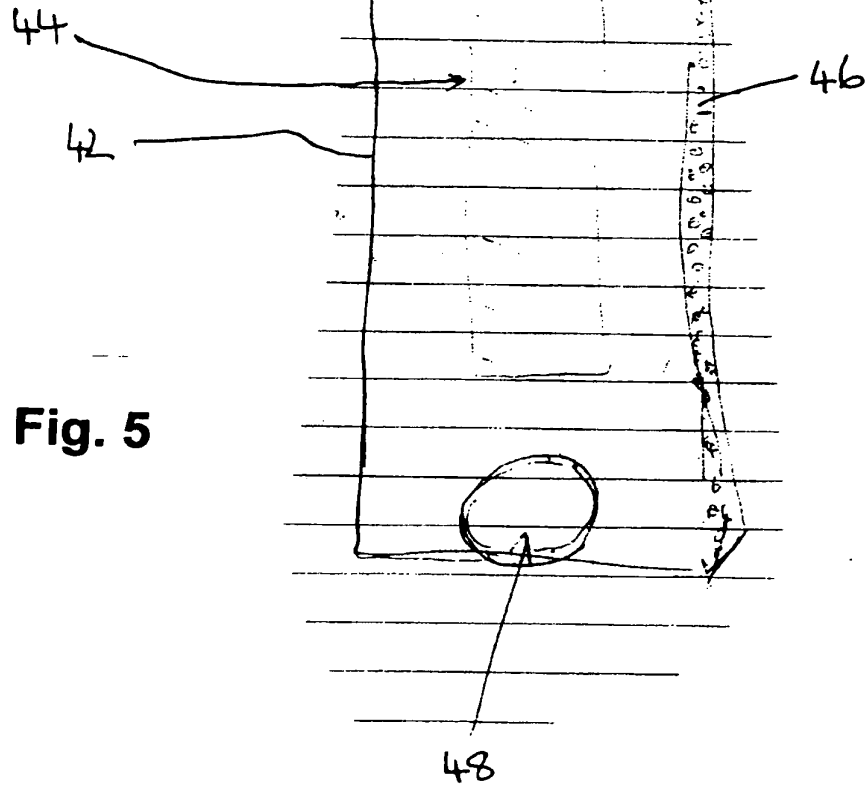


Fig. 5

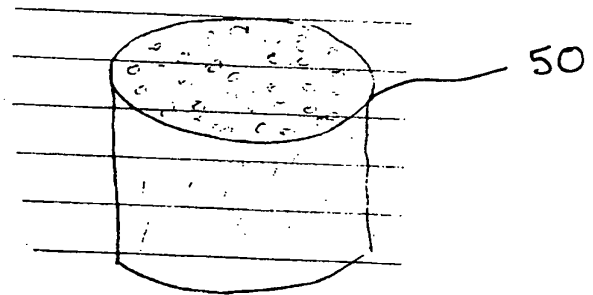


Fig. 6



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hereby certify that annexed is a true copy of the Provisional specification in
connection with Application No. 2006902251 for a patent by FRED BERGMAN
HEALTHCARE PTY LTD as filed on 02 May 2006.



WITNESS my hand this
Seventh day of June 2007

A handwritten signature in cursive script, reading 'J K Bryde'.

JANENE BRYDE
MANAGER
EXAMINATION SUPPORT AND SALES

P/00/009
Regulation 3.2

**AUSTRALIA
Patents Act 1990**

2006902251 02 May 2006

PROVISIONAL SPECIFICATION

Invention Title: **MOISTURE MONITORING SYSTEM**

Applicant: **FRED BERGMAN HEALTHCARE PTY LTD**

The invention is described in the following statement:

MOISTURE MONITORING SYSTEM**Field of the Invention**

5 The present invention relates to moisture monitoring. It relates particularly but not exclusively to systems, apparatus and methods for monitoring moisture in absorbent articles such as diapers, incontinence garments, dressings and pads, resulting from wetness events caused by urinary and/or faecal incontinence, and characterising those wetness events detected.

10 Background to the Invention

Incontinence is a condition in which there is uncontrolled release of natural discharges or evacuations. While some forms of incontinence are more widespread, the condition usually affects women, the elderly and the infirm. Urinary incontinence refers to loss of bladder control resulting in involuntary or
15 uncontrolled urination. Other forms of incontinence including faecal or bowel incontinence also exist. In the context of the present application, the term "incontinence" is to be taken to include urinary and faecal incontinence.

A range of different incontinence types are recognised. Stress incontinence
20 refers to involuntary loss of urine immediately associated with coughing, sneezing, lifting, straining or other physical exertion. The term "stress" relates to the mechanical stress of the abdominal muscles compressing the bladder wall, working against weakened sphincter muscles. Childbirth, obesity, constipation and changes in the sphincter muscles after the menopause can aggravate
25 stress incontinence as can the use of some drugs.

Urge incontinence refers to the involuntary loss of urine coupled with a strong desire to urinate. Often the sufferer is unable to reach the toilet before there has been a urine loss. The need to visit the toilet may occur very frequently during
30 the day and often at night also. Urge incontinence is generally caused by an overactive or "unstable" bladder which contracts involuntarily in an attempt to empty. The contractions give rise to an urgent desire to pass urine and uncontrolled leakage occurs before a toilet is reached. Mixed Urinary Incontinence (MUI) refers to involuntary leakage associated with urge

incontinence and also with exertion, effort, sneezing, or coughing associated with stress incontinence.

5 Overflow incontinence refers to involuntary loss of urine associated with a chronically distended and overfull bladder. The bladder may be distended as a result of incomplete emptying which may be caused by obstruction to the outlet of the bladder or as a result of a failure of the bladder muscle to contract properly. Bladder failure of this kind may be caused by disease of the nervous system, by some drugs or by psychological factors.

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Dribble incontinence refers to leakage of urine without warning or provocation. This is a demoralising condition because leakage can occur at anytime and is unpredictable. Persons suffering from dribble incontinence often need to wear protective pads or diapers throughout the day and night. Total incontinence is a term sometimes used to describe continuous leaking of urine, day and night, or periodic large volumes of urine and uncontrollable leaking. Some people have this type of incontinence because they were born with an anatomical defect. It can also be caused by a spinal cord injury or by injury to the urinary system from surgery.

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Functional incontinence occurs where the ability to get to the toilet is impaired either by physical conditions such as arthritis, or mental impairment. This is very common in nursing home patients who rely on assistance from others to move around.

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Although incontinence is relatively widespread, it is a condition which must be treated with sensitivity as it can be uncomfortable and embarrassing for sufferers and carers alike. When left unchecked, incontinence can become more embarrassing due to the existence of unpleasant odours associated with incontinence events and this can create an unpleasant environment for others in the vicinity of the incontinence sufferer. In addition, exudate escaping the body as the result of an incontinence event often contains bacteria, so unchecked wetness can create health and hygiene problems. Also, health

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regulations or protocols may prescribe a maximum period, for example 15 minutes, for which a patient suffering incontinence may be left in a wet state.

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5 In the past, to comply with such requirements and to ensure that patients in care institutions including hospitals, nursing homes, aged care facilities and geriatric institutions are well looked after, it has been necessary for staff to manually check each patients suffering from incontinence for wetness on a regular basis. Apart from the unpleasantness often experienced by staff and patients in carrying out such manual checks, such a regimen also places a strain on staff resources. Often such checking will also cause interruption to a patient's rest and sleep.

15 Whilst incontinence indicators and detection systems exist, they have done little to improve the current situation in which carers must manually and regularly check patients for wetness. The present invention aims to improve upon such known systems, or at least provide a useful alternative.

Summary of the Invention

20 In a first aspect of the present invention, there is provided a moisture monitoring system for use with one or more absorbent articles. The system includes one or more sensors each of which is adapted for detecting wetness, and processing means. The processing means processes signals from each of the one or more sensors, and performs an analysis of the signals to characterise one or more wetness events occurring in each of the absorbent articles. Each absorbent article is associated with at least one of said sensors. Preferably, the system includes means for communicating to a carer automatically, a signal indicating that a wearer of an absorbent article requires attention.

30 Preferably, the processing means executes an algorithm to perform the analysis, and the algorithm combines one or more data types including wetness data and location data to characterise a wetness event. The processing means may correlate data obtained from a sensor with parameters which characterise certain wetness events. Characterising a wetness event may include any one or more of determining the nature of discharge in a wetness event, estimating a

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degree of fullness of an absorbent article and estimating when an absorbent article is likely to reach its absorbent capacity. Preferably, the processing means uses the sensor signals to recognise lingering wetness in a region of an absorbent article.

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Preferably, the processing means is also configured to log data from the sensors over a period of time, and the system includes storage means to store the logged data obtained from sensors in the system. This enables more powerful analysis which may be utilised to provide an indication of a toileting or voiding schedule suitable for a wearer of an absorbent article. Analysis of the logged data may also provide an indication of an incontinence type, by correlating patterns identified in the logged data. Incontinence types may include, for example, stress incontinence, urge incontinence, faecal incontinence and dribble incontinence. The processing means may be affixable to an absorbent article or to a garment worn by a wearer of the absorbent article.

In one embodiment, the processing means is provided by a central processor adapted to receive sensor signals from a plurality of sensors of the system associated with different wearers of absorbent articles. Each of the sensors communicates sensor signals to the central processor using a transmitter coupled to the sensor. Preferably the transmitter is re-useable and releasably couplable to the sensor which may be disposable.

Preferably, the sensor includes a plurality of spaced apart conductive elements. Features of one such sensor suitable for use with the monitoring system follow.

According to another embodiment of the present invention there is provided a sensor for use with an absorbent article being monitored for moisture, the sensor including a plurality of spaced apart conductive elements arranged in a pattern which provides an improved ability to detect wetness. The sensor may be incorporated into an absorbent garment such as a diaper, nappy, incontinence garment or pad wearable by a user, or may be provided on a liquid

permeable substrate affixable, by adhesive or other fixation means, to an absorbent article. Preferably, the sensor is disposable.

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5 The sensor pattern may include more and/or larger conductive elements in regions having higher propensity for wetness and fewer and/or smaller conductive elements in regions having lower propensity for wetness. Preferably, the pattern includes conductive elements located at 2 or more depths. Preferably, the sensor includes conductive elements detecting wetness at a plurality of locations on the absorbent article. The locations may include, for

10 example, toward the front of the absorbent article, toward the rear of the absorbent article, toward the left and/or right sides of the absorbent article and in the middle of the absorbent article. Preferably, the sensor includes conductive elements positioned toward the sides of the absorbent article, near the leg openings to detect urinary wetness events occurring when a wearer of

15 the absorbent article is lying on the side, although it is preferable that the pattern of the conductive elements is such that the sensor is able to detect wetness events occurring for a user in any position including standing, sitting, lying prone, lying supine and lying on the side.

20 The conductive elements may be made from any suitable material or combination of materials which may include a conductive ink, conductive polymer, conductive thread, conductive tape, a carbon film or fibre and an inert metal. Preferably, the conductive elements are arranged in a 3 dimensional array, and can detect flow of discharge from a wetness event in two or more

25 directions. The sensor pattern may include elongate conductive elements, conductive element dots, conductive elements arranged in a grid or any other arrangement of conductive elements. In one embodiment, the sensor further includes means for detecting one or more of temperature, odour, gas and presence of a biological or chemical marker in exudate in a wetness event.

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According to another aspect of the present invention, there is provided a method for monitoring moisture in an absorbent article including providing an absorbent article having a sensor for detecting wetness or applying a sensor for detecting wetness to an absorbent article, obtaining signals from the sensor, the

signals indicating wetness in the absorbent article, and using processing means to perform an analysis of the sensor signals to characterise one or more wetness events detected.

- 5 Preferably, the processing means logs data from the sensor over time, and performs an analysis of the logged data. The processing means may use wetness data and position data to characterise a wetness event along with other data types when necessary. Preferably, processing means is configured to received sensor signals pertaining to wetness events in absorbent articles
10 worn by a plurality of wearers, and performs analysis for each of the wearers.

Brief description of the drawings

The present invention will now be described in greater detail with reference to the accompanying drawings. It is to be understood that the particularity of the
15 accompanying drawings does not supersede the generality of the preceding description of the invention.

Figure 1 illustrates a moisture detection system according to an embodiment of the present invention.

Figure 2 is a schematic illustration of a diaper or adult incontinence
20 garment laid flat, showing a pattern of conductive elements of a sensor, according to an embodiment of the present invention.

Figures 3A to 3D illustrate plots of resistance over time for different incontinence events, taken from a sensor having conductive elements arranged at different locations on a diaper or adult incontinence garment, i.e. front, back,
25 middle, left side and right side.

Figure 4 is a table showing some example combinations of sensor data which may be correlated with certain wetness events.

30 Detailed Description

In one aspect, the present invention provides a system for monitoring moisture in an absorbent article such as a pad, diaper, adult incontinence garment or the like. Throughout this description, reference will be made to a range of absorbent articles. It is to be understood that the list of wearable absorbent articles

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identified above is not an exhaustive list and that other absorbent articles and garments are within the scope of the present invention. It is also to be understood that a reference in this specification to any one such article, such as a "diaper" is to be taken to be a reference to any and all other suitable absorbent articles including incontinence garments, pads and the like.

The system preferably provides useful information generated by a processor which analyses signals from one or more sensors applied to or manufactured within a diaper. desirably, the sensor or sensors each include an array of conductive elements arranged to detect wetness resulting from conditions such as urinary or faecal incontinence, perspiration or other wetness events.

The moisture monitoring system of the invention is generally intended for use in facilities in which staff are required to monitor and care for individuals who suffer from various incontinence conditions. These facilities include hospitals, nursing homes, aged care facilities, geriatric institutions, private homes, respite centres and the like, although it may also be used in other environments.

As well as the urinary and faecal incontinence and wetness events referred to above, the present invention also has applicability in the detection, monitoring and management of conditions in which other fluids and exudates from the body may be present, including wound management.

Figure 1 is a block diagram illustrating features of a moisture detection system shown generally at 100 according to a preferred embodiment of the present invention. The system includes a plurality of sensors 102 each being associated with a different patient. Each sensor is in communication with a transmitter 104 which wirelessly transmits a signal to a receiver 112 which is in communication with a processor 106. The transmitter 104 may also include a pre-processor for processing signals prior to transmission to the receiver.

The processor includes display means 106a and input means 106b which can be observed and manipulated by a nurse or other user of the system to obtain information from the processor including characterisation information relating to

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wetness events being detected by the sensors in the system. Users may also enter data (e.g. the identity and room number of a patient) and re-set sensor data for a particular patient when, for example, a soiled diaper has been replaced or a patient moves rooms or is discharged. Preferably, the processor 106 is incorporated into a central monitoring station such as a nurse's station. The processor may also integrate with or be incorporated into existing nurse call and remote patient monitoring systems controlled at the nurse's station. The processor may also be integrated with other care management systems whereby information collected from the sensors of the system can be combined with information collected from those other systems relating to, for example, fluid intake, patient relocation, showering, toileting, treatments etc.

The system may also include a transmitter 108 in communication with the processor. The transmitter 108 sends alerts wirelessly to communication devices carried by carers 110 to alert them when certain pre-defined conditions have been identified by the processor in the analysed signals. These conditions may include, for example, when a diaper has absorbed a total volume of urinary exudate over a period of time which is approaching the diaper's absorbent capacity (i.e. the diaper is approaching fullness). For sensors having diagnostic capability, a pre-defined condition may include when a parasite or biological indicator has been detected in the urine or faeces.

Figure 1 illustrates a preferred embodiment in which the monitoring system is wirelessly enabled for communication with a number of sensors allocated to a number of different patients being monitored. However, it is to be understood that in an alternative arrangement, the part of the processor performing the analysis may be located near the sensor, on the absorbent article. Thus, the sensor and the part of the processor performing the analysis may be provided together, and incorporate a transmitter to transmit data from the processor to another part of the processor preferably including a display located at the central monitoring station/nurse's station.

Preferably, transmitters 104 are re-useable, and are releasably connectable to the sensors. This connection may utilise any suitable connection means such

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as a male-female dual-in-line (DIL) connector or the like, as would be known to a person skilled in the relevant art. The transmitters are then attached to a diaper or to clothing worn by the patient in a manner which is comfortable for the patient to wear, and is also sufficiently robust to minimise the risk of damage or removal while in use. When the diaper/incontinence garment is changed, the transmitter is disconnected from the soiled sensor, cleaned and attached to a sensor on a new diaper/incontinence garment.

Alternatively, the transmitter and sensor may be disposable and incorporated into a diaper or a sensor-pad/sensor-liner attachable to a diaper. In such arrangement, the sensor can be activated by a switch or button which is felt through the layers of the diaper. Alternatively, a radio-frequency identification signal emanating from the sensor can be read by a device, preferably located at a central monitoring station, to commence monitoring of signals from the sensor. In a further alternative embodiment, all parts of the monitoring system are re-useable, although this may create hygiene problems and be undesirable for individuals left with the task of cleaning the components.

The sensor and other components which are located on the diaper (e.g. transmitter, pre-processor) are preferably powered by a small battery or electronic component storing energy. To conserve power, the sensor may deactivate when the diaper has not received a wetness event for a predetermined length of time. The sensor may then be reactivated upon detection of wetness in which a conductive bridge between conductive elements of the sensor is established.

The processor analyses signals received from the sensors to characterise wetness events which are detected for each patient. Characterisation of wetness events by the processor may include characterising the cause of a wetness event by making a distinction between wetness resulting from incontinence, perspiration or other leakage or discharge which may occur due to bedsores or decubitous ulcers which can develop in immobile patients. Characterisation may also include identifying the nature of exudates released in a wetness event. That is, distinguishing a urinary wetness event from a faecal

wetness event. Processing may be performed by a processor on a host computer or by a processor embedded with the transmitter unit.

Preferably, the processor executes an algorithm defined in software to perform the analysis, although it is to be understood that the processor may be programmed in software or in hardware using a range of different techniques and languages as would be known to a person skilled in the relevant art. Advantageously, the algorithm enables the processor to combine different types of data which can be obtained from the sensor signals, and analyse that data to characterise a wetness event, thereby providing more useful information to a user of the system.

A sensor 102 may be incorporated into a pad, diaper or adult incontinence garment, or it may be provided in a separate article such as a sensor-pad/sensor-liner which can be applied to an "off the shelf" pad, diaper by way of adhesive or other fixation means. For a liner, it is preferable that the substrate and layers of the liner are liquid permeable so that exudate released by the wearer passes through the liner (activating conductive elements of the sensor) and is then drawn away from the user, into the absorbent layers of the diaper to which the liner is attached. Pores and channels may be provided in the substrates to facilitate drawing exudate away from the skin surface into the diaper to which it is affixed.

The sensors 102 each preferably include an array of conductive elements capable of detecting moisture. When an electrolyte such as urine contacts the conductive elements in sufficient quantity, a conductive bridge is formed between the affected elements and this can be detected by monitoring one or more electrical characteristics of the elements such as resistance or conductance, capacitance or the like. The conductive elements may be formed using any suitable conductive materials or combinations of materials including conductive inks, polymers, tapes, resins and threads, other suitable conductive polymeric materials, conductive film, fibres or electrodes including, for example, an inert metal.

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Production of the sensor may utilise a range of manufacturing methodologies. One example is screen printing which can be employed to deposit the conductive elements on a suitable substrate. For three-dimensional arrays, the conductive elements may be deposited on a number of substrate layers which are then bonded into a multilayer liner. For conductive elements incorporated into diapers, depositing the conductive layers on the various absorbent layers of the diaper can be integrated into the diaper manufacturing process.

The conductive elements may be elongate or provided in the form of grids, dots or the like, arranged in a pattern along and/or in the diaper or a pad or liner attachable thereto. By utilising, for example, screen printing techniques, effective patterns can be designed and printed in layers of the sensor quickly and accurately. Advantageously, screen printing can deposit conductive polymers, inks and the like in very fine lines or grids between which exudates including urine and faeces may be absorbed into deeper, more absorbent layers. This enables the conductive elements of the sensor to be incorporated into a diaper or absorbent article without significantly affecting the extent to which exudates are absorbed by the deeper layers of the diaper.

The conductive elements of the sensor are preferably provided in a quantity and pattern sufficient to enable detection of moisture in different locations in an absorbent article being worn by a user. The pattern may be a two-dimensional pattern in which the sensors are provided in a single layer or in a three-dimensional pattern. The pattern of the conductive elements is preferably such that the elements are focussed in regions of the article where there is a greater likelihood of them being affected by exudates resulting from a wetness event. Figure 2 is a schematic drawing of a diaper 200 laid flat, showing one example of a pattern of conductive elements which may be suitable. Preferably, each of the conductive elements can be uniquely identified enabling a sensor to convey to the processor data indicating that wetness is present, as well as the location of the conductive element(s) detecting the wetness. This enables the processor to determine where in the absorbent article and the extent to which the wetness has occurred.

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In a preferred embodiment, the sensor has a plurality of layers and the conductive elements are arranged in a three-dimensional pattern within the layers. A three-dimensional array is advantageous for a number of reasons. Firstly, absorbent articles such as diapers are flexible in nature and therefore prone to folding or scrunching particularly in regions around the legs. To circumvent a problem in which 2 or more conductive elements are caused to "short" together as a result of a fold in the article or movement of a wearer, adjacent conductive strips may be placed in alternate layers of the sensor, separated by an electrically insulating permeable layer to prevent shorting in the absence of wetness.

Secondly, by positioning conductive elements in different layers of the sensor, it is possible for the sensor to convey additional location data to the processor relating to the depth at which moisture is detected. This is particularly important for sophisticated diapers and incontinence garments which are multi-layered in their construction and designed with super absorbent and "wicking" properties to draw wetness away from the wearer and direct it to chambers or zones in the absorbent layers where it is retained. Positioning conductive elements in or near various absorbent layers of the article can convey further relevant data to the processor which may relate to, for example, the degree of wetness (or fullness) of a storage chamber within a diaper. Also, elements located at various depths allow the system to monitor the absorption of fluid into a diaper. Thus, the sensor will not require 'pooling' (i.e. spread) of liquid in a layer before it is absorbed through layers of the garment to result in detection of moisture. This is especially useful in view of the fact that most absorbent garments are manufactured to maximise the absorption of liquid away from the skin.

As indicated above, the conductive elements are arranged in a pattern which maximises the sensor's ability to detect relevant data, for use in characterising wetness events. For example, as illustrated in Figure 2, the pattern may provide conductive elements more densely in a region toward the front of the absorbent article (202), to the rear of the absorbent article (204), and around the leg openings (206) and in the centre, between the leg opening (208), where liquid is likely to drain. Positioning the conductive elements in this way improves the

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detection of urinary wetness which normally occurs toward the front of an absorbent article, detection of faecal wetness which normally occurs to the rear of an article, and detection of wetness resulting from perspiration which can frequently occur, for example, toward the sides in the crotch area near the crease of the wearer's legs, and toward the middle of the diaper.

The sensor may also provide means to detect temperature, pressure, presence of a gas or odour in the absorbent article and/or the presence of a biological or chemical marker indicating presence of bacteria, sugar, parasites or the like in the urine or faeces. This is particularly useful for patients who lack the ability to control where and/or when a voiding event will occur. Data pertaining to these further parameters can also be used, in combination with signals from the conductive elements to further characterise a wetness event, provide a diagnostic indicator, or at least give a carer an early indication that a particular patient is in need of further attention.

The moisture detection system preferably logs the sensor data over time, providing continual monitoring for the duration that an absorbent article is worn by a user. Preferably, the processor has inbuilt functionality with which it is programmed to provide an alert when certain pre-defined conditions are met during the monitoring of a patient for wetness. These include conditions such as when a diaper has been affected by an estimated volume of exudate approaching the absorbent capacity of the diaper (fullness) and is due to be changed, or when a biological or chemical constituent has been detected in the exudate. The alert may be audible and/or visual, and preferably transmits a message via the transmitter 108 to a pager or other communication device carried by an assigned carer 110 so that the carer knows to attend to a particular patient.

The processor preferably maintains a log of data received from all the sensors in the system and correlates the data with a range of parameters which are known to characterise certain wetness events. The sensor signals are logged regularly, say, every 100 milliseconds or sufficiently frequently to reliably and accurately detect and distinguish an event. Signals received by the processor

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can reveal data indicating for example (i) detection of wetness and (i) location of the detected wetness. These signals can vary over time, as liquid is absorbed though the diaper and further wetness events occur. By monitoring these signals in time, it is possible for the processor to derive further useful parameters such as volume of exudate in an event and total volume absorbed.

By monitoring the rate of change of an electrical characteristic, such as resistance, of the conductive elements as well as the rate of flow between adjacent or proximal conductive elements, it is possible to determine the location and rate of flow of exudate. This, in combination with location data for the affected elements, can be used by the processor to provide an indication that the wetness event is a urinary event, a faecal event, or a perspiration event. Also, the volume of exudate released can be computed using such factors as the distance between conductive elements detecting the wetness, the rate of transfer of moisture between these elements and the absorption properties of the materials used. These materials may include polymer fibres, natural fibres, gels, textiles, fabrics, papers or a combination of these materials.

Preferably, the processor is programmed with or can interrogate a database of "event signatures" or models characterising certain wetness events and correlates the signals from the sensors with the event signatures/models to characterise wetness events which are detected. The models may be embodied in any form including mathematical models characterising wetness events, graphs or look up tables. These models may involve deriving further data from the sensor signals such as flow rates and estimated volumes.

Figures 3A to 3F show changes in resistance over time for a range of conductive elements located at different positions in a diaper. Formation of a conductive bridge between conductive elements results in a decrease in resistance which is therefore indicative the presence of wetness. These figures include logged data from conductive elements located in the middle, toward the front, toward the left side, toward the right side and toward the rear of a diaper. These plots may be considered indicative of a type of graphical event signature which may be used to characterise certain wetness events.

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- Figure 3A shows a possible event signature for an overflow urinary incontinence event. In this example, urine is released regularly over time and the exudate is detected by conductive elements at the front and toward the middle of the diaper shown by a rapid decline in resistance at these elements. This is followed by a quick increase (recovery) in resistance as the wetness is drawn away from the conductive elements and into deeper and more absorbent layers of the diaper.
- Figure 3B shows a possible event signature for a stress or urge urine incontinence event. Again, this is also characterised by a rapid decrease in resistance at front and middle conductive elements, followed by rapid recovery (for a diaper which has not yet reached its absorbent capacity).
- Figure 3C shows a possible event signature for a perspiration wetness event. In this event, conductive elements located toward the left and right sides and toward the middle of the diaper detect wetness. The slower decrease of resistance indicates that there is a slow rate of flow of moisture onto the conductive elements. The higher resistance values and the short time-span of the event indicates less moisture being present (if at all). The moisture is then drawn away from the conductive elements, as indicated by an increase (recovery) in resistance. Since the moisture has been detected by a slower decrease in resistance (due to a slower flow rate), and it has been detected at the middle and side elements and not the front element, the event can be characterised as a "perspiration event" rather than a urinary incontinence event.
- Advantageously, by including laterally placed conductive elements in the sensor pattern, incontinence events can be detected irrespective of whether the patient is in the sitting, lying or standing position. For instance, if the patient is lying on his side, laterally located conductive elements are more likely to detect urinary exudate than the frontal elements which would be activated if the patient was standing or sitting.

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Figure 3D shows a possible event signature for a faecal wetness event. In this event, conductive elements located toward the rear and middle of the diaper are activated. It can be seen from Figure 3D that the rate of decrease in resistance detected by these elements is slower than the rate of decrease for urine. This is due to the lack of moisture in the faecal matter and the slow rate of absorption across the conductive elements. Typically, faecal matter would also have a lower electrolyte content than urine and this would result in a higher resistance value being measured than would be the case if urine was being absorbed. However, electrolytic content of exudates including urinary and faecal, are dependent on various conditions and are therefore prone to vary between patients and between wetness events. Also, as can be seen From Figure 3D, the rear conductive element detects the moisture before the middle element. This location data is also indicative of a faecal event.

Moreover, lingering wetness is indicated by the failure of the resistance to recover (increase). A prolonged decrease in resistance can be indicative of faecal matter which, unlike urine, is not drawn into the absorbent layers of the diaper but remains in contact with the conductive elements. Detection of a faecal event should be accompanied by an alert to a carer to change the diaper so as to avoid prolonged wetness and discomfort. A lingering wetness may also be indicative of a full diaper, resulting from inability of the diaper to draw any more urine away from the wearer. This condition should also be communicated to a carer.

It is to be understood that the event signatures illustrated in Figures 3A to 3D are illustrative only and are not to be taken as limiting on the scope of the invention, or the capability of the processor to characterise different wetness events. In addition to being able to detect the presence of exudate and its location, the sensors may also include means to detect temperature and the presence of odour, gas, pressure, biological elements such as bacteria and parasites and chemical constituents such as glucose and urea in the exudates. Input to the processor pertaining to these parameters can be combined with the wetness and location data to further characterise a wetness event. The table presented in Figure 4 describes some combinations of sensor data which may

be correlated with certain events, enabling the processor to characterise wetness events detected by sensors in the system.

A urinary incontinence event can be characterised by a wetness event in which there is a release of small to larger volumes having high viscosity. This means that the incontinence event occurs quickly, and the exudate is drawn away from the wearer into the absorbent layers of the diaper fairly quickly. This is characterised by (as was seen in Figures 3A and 3B) a rapid decrease in resistance followed by a fairly quick recovery once the wetness event has concluded.

As can be seen from the details provided in the table of Figure 4, by monitoring the frequency and volume of urinary incontinence events over time, it is possible for the processor to correlate various sensor signals with different types of incontinence types such as overflow incontinence which is associated with frequent and brief urinary wetness events in which exudate is released near the front and middle of diaper and may affect the sides of the diaper if patient is lying on her side. Urinary stress incontinence may also be identified by correlating received sensor signals indicative of urinary wetness events of small to medium volume occurring coincidentally with the patient moving. Urinary urge incontinence may be identified by correlating received sensor signals indicative of urinary wetness events of medium to large volumes of lower frequency. If the person has not urinated for a few hours, then they might have a larger volume event than of they had urinated in the previous 15 minutes which can be further correlated with the amount and type of liquid being consumed by the patient.

Faecal wetness events may be identified by correlating received signals indicative of lingering wetness located toward the rear and possibly middle of the diaper. These indications can be combined with detections of sustained increased temperature, odour and/or gas.

Perspiration wetness events can be identified by correlating received signals indicative of small volumes of wetness creating numerous detections, usually

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toward the sides and middle of the diaper, in the crotch area. These indications may be further correlated with periods of atmospheric warmth, fever in the patient and a rise in temperature detected in the vicinity of the detected wetness.

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In time, wetness events detected by the sensor and analysed by the processor can be used to provide carers with useful information including an indication of when a patient's diaper has reached its absorbent capacity and is ready to be changed. This can be identified by correlating received signals indicative of numerous urinary incontinence events having taken place over time, and a lingering wetness located at various locations in the diaper since it is no longer able to draw wetness away from the wearer.

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Preferably, the processor also correlates the estimated volume of exudate released by the patient over the period of monitoring, and compares the volume with the estimated capacity of the diaper to give carers an indication of when the diaper is likely to become saturated with exudate so that it can be changed before a saturating wetness event occurs and the patient is made to feel uncomfortable by excess wetness.

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The processor may be configured to receive data (either entered manually or automatically by, for example, scanning a barcode on a diaper) pertaining to known features of a diaper or incontinence garment being worn by a patient. The features may include the structure of the diaper/garment, the approximate rate of absorbency in regions of the diaper/garment, as well as the location of conductive elements of the sensor embedded therein. This data enables the processor to model the diaper/garment and, when used in combination with the data received from the sensor can enable the processor to perform powerful analysis. Because the processor uses wetness and location data and algorithms to characterise wetness events, it is also able to characterise phantom events or noise, which may result from the patient moving or from intermittent brief interference from other components in the system, and disregard these artefact points.

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The processor can also use the log of data obtained over a period of time to automatically identify patterns which are used to develop toileting and voiding schedules designed to plan when to empty the bladder or bowel, prior to the periods in which a patient is known to experience incontinence events.

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It is to be understood that various modifications, additions and/or alterations may be made to the parts previously described without departing from the ambit of the present invention as defined in the claims appended hereto.

- 10 Future patent applications may be filed in Australia or overseas on the basis of or claiming priority from the present application. It is to be understood that the following (provisional) claims are provided by way of example only, and are not intended to limit the scope of what may be claimed in any such future application. Features may be added to or omitted from the (provisional) claims
- 15 at a later date so as to further define or re-define the invention or inventions.

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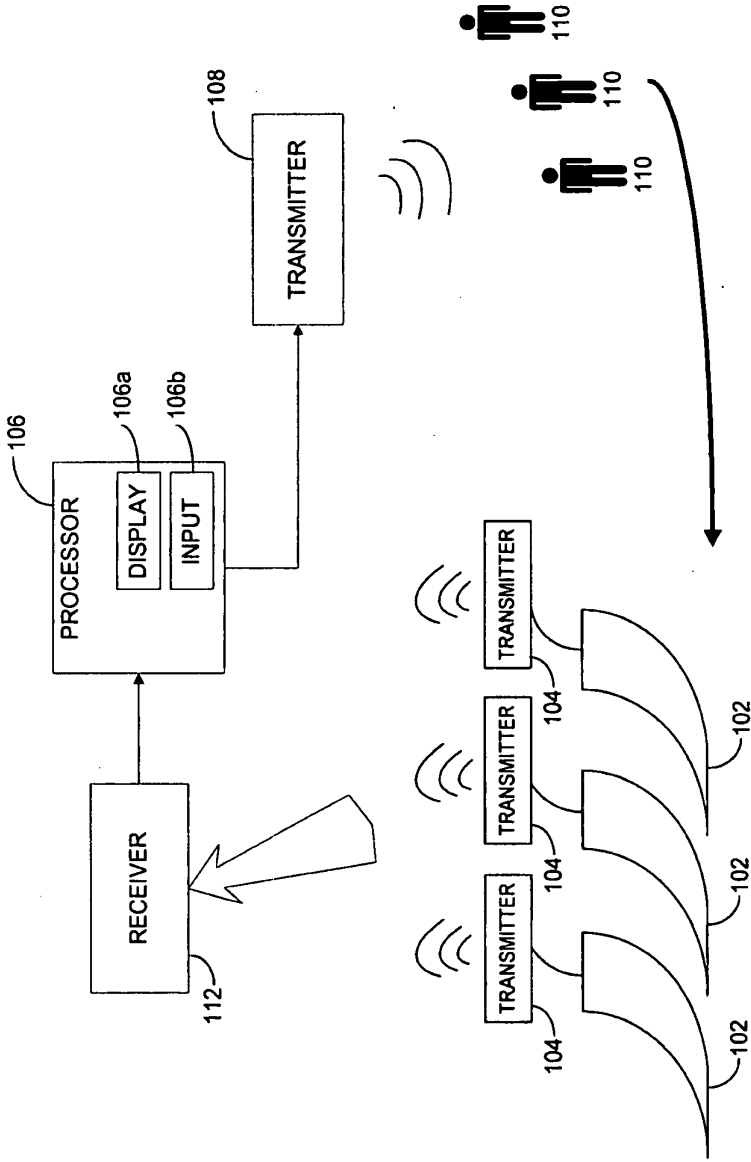


Figure 1

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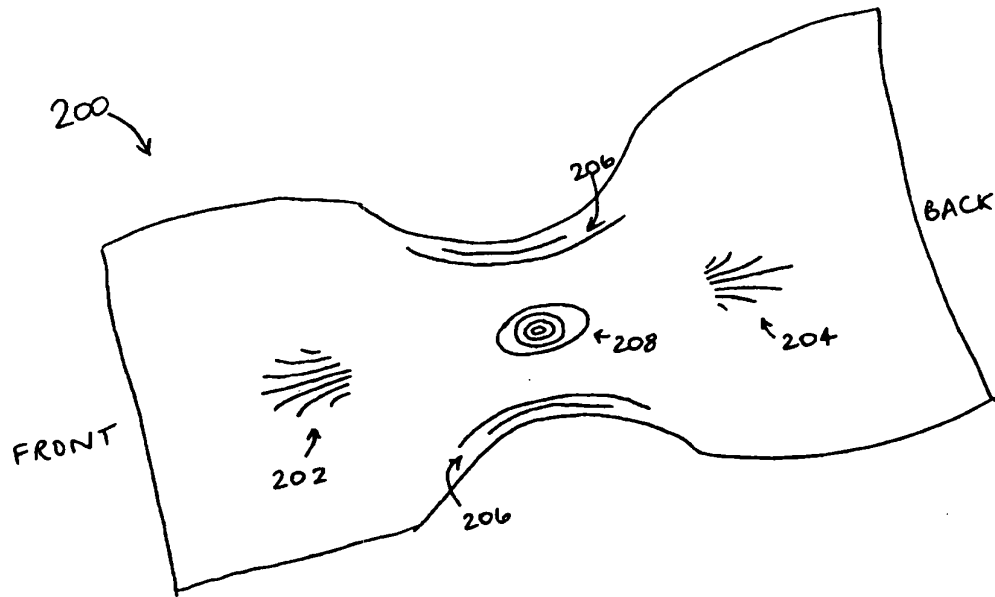


Figure 2

2006902251 02 May 2006

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2006902251 02 May 2006

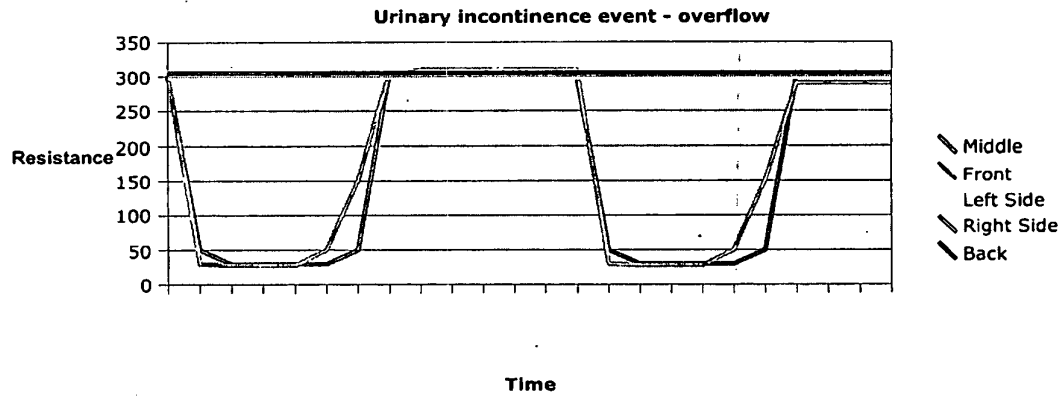


Figure 3A

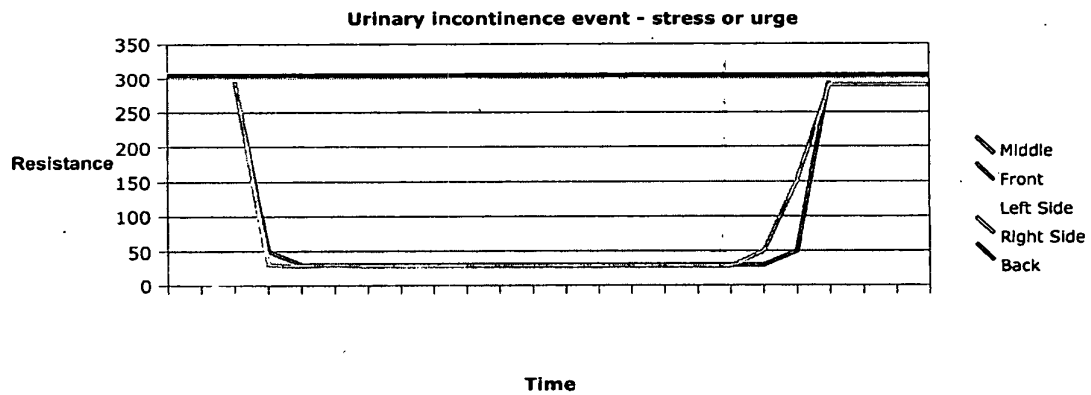


Figure 3B

2006902251 02 May 2006

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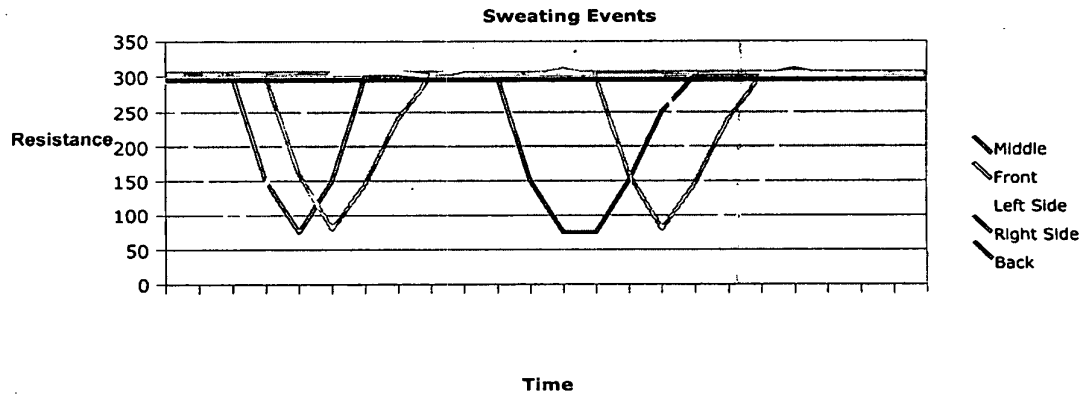


Figure 3C

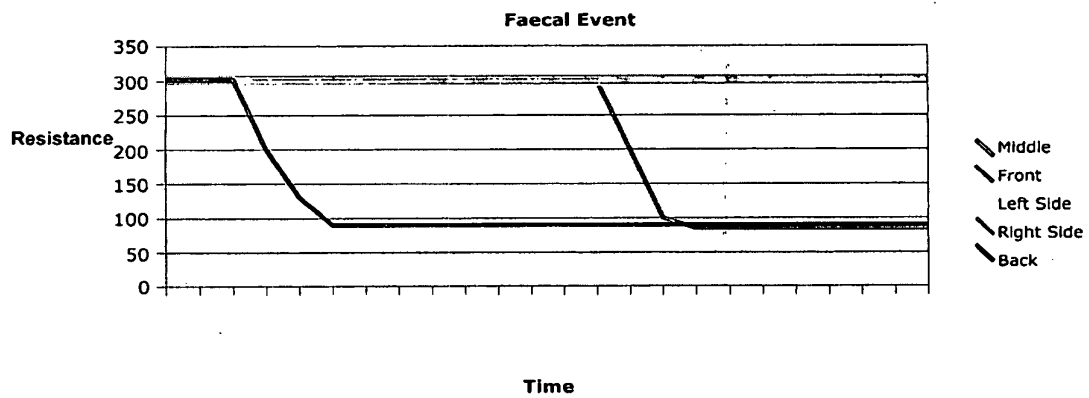


Figure 3D

2006902251 02 May 2006

5/5

TYPE OF EVENT	FEATURES OF EVENT	DURATION OF SENSOR DETECTION	SENSITIVITY OF SENSOR DETECTION	DEGREE OF SENSOR DETECTION	LOCATION OF SENSOR	TYPE OF SENSOR
Urinary incontinence - overflow	frequent brief wetness events of small volume in locations concurrent with urinary leakage (i.e. front and middle, sides if patient lying on side)	brief and frequent	immediate	small to medium	generally front or middle but maybe side if resident is lying on side	moisture, temperature
Urinary incontinence - stress	small to medium volume wetness events in locations concurrent with urinary leakage, at times coinciding with patient moving/other activity	variable proportional to volume	immediate	medium to high	generally front or middle but maybe side if resident is lying on side	moisture, temperature
Urinary incontinence - urge	medium to large volume wetness events in locations concurrent with urinary leakage, frequency depends on amount and type of liquid consumed and a sizeable period since the last event	variable proportional to volume	immediate	medium to high	generally front or middle but maybe side if resident is lying on side	moisture, temperature
Perspiration	small volume and possible intermittent wetness events, may coincide with periods of atmospheric warmth and possible fever in vicinity of the detected wetness	brief and frequent	gradual	small	sides and middle	moisture, temperature
Faecal	sustained wetness event of small volume/lower conductivity due to lack of moisture in the faecal matter	sustained and infrequent	variable	Low to medium	Back (and possibly middle)	moisture, temperature, gas/odour
Diaper is full	Results from numerous urinary continence events of duration concurrent with a total volume sufficient to fill the diaper's absorbent capacity. Also sustained detection of moisture would indicate a full diaper since wetness can no longer be drawn away from the skin's surface	sustained infrequent following previous events of sufficient duration (volume)	sustained	medium to high	a majority of locations	moisture
Noise	brief events of positive detection which may coincide with moving, changing or random activities	brief	-	-	-	-

Figure 4



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APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	TOT CLAIMS	IND CLAIMS
11/797,352	05/02/2007	3761	2440	P71951US0	79	7

CONFIRMATION NO. 6338

UPDATED FILING RECEIPT

136
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC20004

Date Mailed: 08/02/2007

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Applicant(s)

Frederick Bergman, Caulfield, AUSTRALIA,
 Deceased;
 Ari Bergman, Caulfield, AUSTRALIA, Legal
 Representative;
 David Albert Barda, Docklands, AUSTRALIA;
 Daniel Weinstock, Caulfield South, AUSTRALIA;
 Remi Guibert, Mount Martha, AUSTRALIA;
 Maria C. Rodda, Mount Eliza, AUSTRALIA;
 Guy Eitzen, Wheelers Hill, AUSTRALIA;

Power of Attorney:

Harvey Jacobson Jr--20851	Jonathan Scherer--29851
John Holman--22769	William Player--31409
Nathaniel Humphries--22772	N Wilson--38661
Michael Slobasky--26421	Suzin Bailey--40495
Allen Melser--27215	

Domestic Priority data as claimed by applicant

This application is a CIP of PCT/AU05/01667 10/28/2005

Foreign Applications

AUSTRALIA 2006902251 05/02/2006
 AUSTRALIA 2004906315 11/03/2004

If Required, Foreign Filing License Granted: 05/25/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is
US11/797,352

Projected Publication Date: 11/08/2007

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Incontinence management system and diaper

Preliminary Class

604

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For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

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Date Mailed: 08/16/2007

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US11/797,352

Projected Publication Date: 11/22/2007

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

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Preliminary Class

604

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APPLICATION NUMBER	FILING OR 371(c) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
11/797,352	05/02/2007	Frederick Bergman	P71951US0

CONFIRMATION NO. 6338

136
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC20004

Title: Incontinence management system and diaper**Publication No.** US-2007-0270774-A1**Publication Date:** 11/22/2007**NOTICE OF PUBLICATION OF APPLICATION**

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

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Pre-Grant Publication Division, 703-605-4283



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

F. BERGMAN et al.

Group Art Unit: 3761

Serial No.: 11/797,352

Examiner: Unassigned

Filed: May 2, 2007

Confirmation No.: 6338

For: INCONTINENCE MANAGEMENT
SYSTEM AND DIAPER

FIRST INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
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Sir:

As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicant(s), through the undersigned attorney, submits this Information Disclosure Statement. The patents, publications or other information submitted herewith are listed on the attached Form PTO-1449 and copies are attached excluding U.S. patents and publications.

The documents listed on the attached Form PTO-1449 are being brought to the Examiner's attention in compliance with the Duty of Disclosures.

In accordance with 37 CFR §1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits of the above-identified application.

IPW

U.S. Patent Application No. 11/797,352

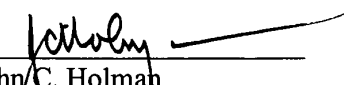
Page 2

Should any additional fee be required by the filing of this statement, please charge such fee to
Deposit Account No. 06-1358.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: _____


John C. Holman
Registration No. 22,769
400 Seventh Street, N.W.
Washington, DC 20004-2218
(202) 638-6666

Atty. Dkt. No.: P71951US0
Date: September 30, 2008

FORM PTO-1449 (Modified)

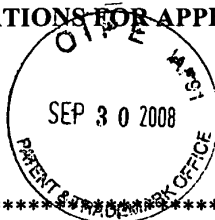
Sheet 1 of 3

JACOBSON HOLMAN PLLC
400 SEVENTH STREET, N.W.
WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P71951US0
SERIAL NO. 11/797,352
APPLICANT(S): BERGMAN et al.

GROUP ART UNIT: 3761
FILING DATE: May 2, 2007
TODAY'S DATE: September 30, 2008



U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,356,818	11/02/82	Macias et al.			
	AB	4,507,121	03/26/85	Leung			
	AC	4,539,559	09/03/85	Kelly et al.			
	AD	4,977,906	12/18/90	Di Scipio			
	AE	5,036,859	08/06/91	Brown			
	AF	5,264,830	11/23/93	Kline et al.			
	AG	5,416,469	05/16/95	Colling			
	AH	5,568,128	11/22/96	Nair			
	AI	5,537,095	07/16/96	Dick et al.			
	AJ	5,570,082	10/29/96	Mahgerefteh et al.			
	AK	5,557,263	09/17/96	Fisher et al.			
	AL	5,760,694	06/02/98	Nissim et al.			
	AM	5,790,036	08/04/98	Fisher et al.			
	AN	5,838,240	11/17/98	Johnson			
	AO	5,902,296	05/11/99	Fluyeras			
	AP	5,959,535	09/28/99	Remsburg			
	AQ	6,091,336	07/18/00	Zand et al.			
	AR	6,093,869	07/25/00	Roe et al.			
	AS	6,097,297	08/01/00	Fard			
	AT	6,149,636	11/21/00	Roe et al.			
	AU	6,246,330	06/12/01	Nielsen			
	AV	6,292,102	09/18/01	Smith			
	AW	6,384,728	05/07/02	Kanor et al.			
	AX	6,384,296	05/07/02	Roe et al.			
	AY	6,433,695	08/13/02	Kai et al.			
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	BB	6,573,837	06/03/03	Bluteau			
	BC	6,603,403	08/05/03	Jeutter et al.			
	BD	6,774,800	08/10/04	Friedman et al.			
	BE	6,876,303	04/05/05	Reeder et al.			
	BF	6,916,968	07/12/05	Shapira et al.			
	BG	7,049,969	05/23/06	Tamai			
	BH	7,053,781	05/30/06	Haire et al.			
	BI	7,071,830	07/04/06	Sahlberg et al.			
	BJ	7,141,715	11/28/06	Shapira			
	BK	7,176,344	02/13/07	Gustafson et al.			
	BL	7,221,279	05/22/07	Nielsen			
	BM	7,250,547	07/31/07	Hofmeister			

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Sheet 2 of 3

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P71951US0
 SERIAL NO. 11/797,352
 APPLICANT(S): BERGMAN et al.

GROUP ART UNIT: 3761
 FILING DATE: May 2, 2007
 TODAY'S DATE: September 30, 2008

	BN	2002/0003478	01/10/02	Zhao et al.			
	BO	2003/0011479	01/16/03	Bluteau			
	BP	2003/0060789	03/27/03	Shapira et al.			
	BQ	2004/0220538	11/04/04	Panopoulos			
	BR	2005/0046578	03/03/05	Pires			
	BS	2005/0156744	07/21/05	Pires			
	BT	2006/0139165	06/29/06	Bader			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES) (NO)
	CA	2 361 132	05/07/02	Canada			
	CB	1 047 033	10/25/00	Europe			
	CC	1 063 624	12/27/00	Europe			
	CD	1 567 998	08/31/05	Europe			Abstract only
	CE	2 733 146	10/25/96	France			Abstract
	CF	198 37 678	03/02/00	Germany			Abstract
	CG	WO 97/42613	11/13/97	PCT			
	CH	WO 02/101679	12/19/02	PCT			
	CI	WO 2004/034929	04/29/04	PCT			
	CJ	WO 2004/049969	06/17/04	PCT			
	CK	WO 100763	11/25/04	PCT			
	CL	WO 2005/107580	11/17/05	PCT			
	CM	WO 2006/047815	05/11/06	PCT			

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	DA	Wu et al. "Odor-Based Incontinence Sensor." Robotics Institute, School of Computer Science, 2000, Pages 63-68.
	DB	"Wet-Sense Monitoring System." Technology for Long Term Care. 02/19/06. www.techforltc.org/ltc.cfm?pageid=157&product=820&careissue=3 .
	DC	"SenseSoft." Sensible Solutions. www.sensible-solutions.se/index.php?option=com_content&task=view&id=25&Itemid=36 .
	DD	"Incontinence event data logger." Date Logger. 07/08/00. www.medphys.ucl.ac.uk/udlh-compinst/instrumentation/past/data%20logger.htm .
	DE	"Roke Manor Research Develops Wireless Patient Monitor." Roker Manor Research Limited. April 30, 2003. www.roke.co.uk/press/index.php?id=53&format=print .

FORM PTO-1449 (Modified)

Sheet 3 of 3

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

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	DF	"What Makes the Stay-Dri Continence Management System a System?" The Stay-Dri System. www.staydriSYSTEM.com/home/frames/system.asp .
	DG	"Compare and Review Bed Wetting Alarms." www.enuresisalarms.com/bed-waiting-alarm-reviews-comparision-chart.htm
	DH	"Sensatec® Care 3." Technology for Long Term Care. July 16, 2007. www.techforltc.org/ltc.cfm?pageid=157&product=764&careetissue=3 .
	DI	"Wireless Alarm & Record Wetness Sensor And Toilet Trainer." Malem Medical. www.malem.co.uk/Expand.asp?ProductCode=MO7 .

EXAMINER	DATE CONSIDERED
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s)

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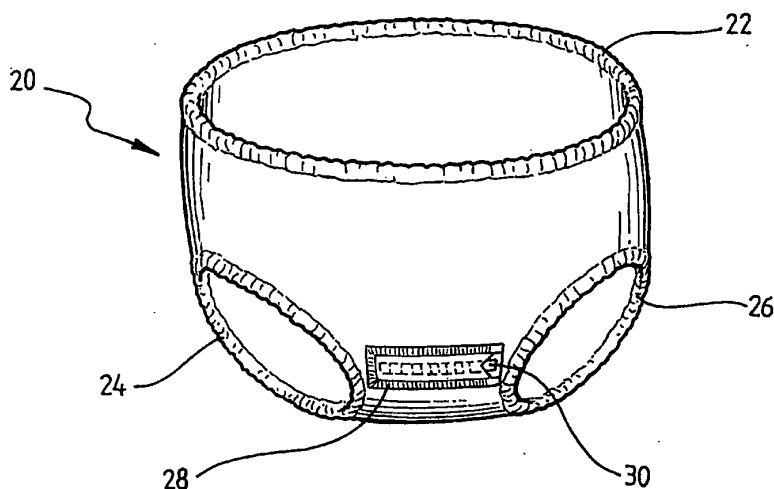
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(54) Title: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER



(57) Abstract: A diaper (20) for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, has a sleeve (28) for the insertion of a diagnostic strip (30) adapted to detect relevant substances in urine or exudates. The sleeve (28) has a V-shaped notch (34) for ease of insertion of a diagnostic strip (30). Pores and channels (36) are provided on the sleeve (28) to facilitate the drawing in of urine from the diaper (20) to the sleeve (28) to contact the strip (30) and expose chemical sensors on the strip (30) to the collected urine. The sleeve (28) may be attachable to the diaper (20) by adhesive material (40).

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INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

This invention relates to a system for managing incontinence, to elements of such a system, and to associated detection, monitoring and treatment systems, methods and apparatus.

5 Incontinence, in the context of this specification, includes urinary and faecal incontinence, and management of such incontinence is to be seen in the context of persons located in hospitals, nursing homes, aged care facilities, geriatric institutions, private homes and the like.

The aforementioned incontinence, when unchecked, may result in the person suffering from the condition experiencing discomfort or at least embarrassment, and in the existence of unpleasant odours and environment for others in the vicinity of the person. In addition, health regulations or protocols may prescribe a maximum period, such as 15 minutes, for which a patient may be left in a wet state caused by incontinence. In the past, to comply with such requirements, it has been necessary for nursing staff to manually check each patient at least once during the prescribed period. Apart from the unpleasantness experienced by nursing staff in carrying out such manual checks, such a regimen may place a severe strain on staff resources, and may constitute an interruption to patients' rest and sleep.

In WO 96/14813 there is described an incontinence management system in which remote sensors are associated with patients, the sensors being responsive to urinary and/or faecal incontinence, and to generate and send signals consistent with such incontinence by radio to a monitor, which monitor receives and records the signals. Such a system enables data to be collected for each patient, to enable any regularity or pattern of incontinence to be determined. Staffing assistance for a patient is also able to be obtained through the system.

US-A-5,291,181 relates to a wet bed alarm and temperature monitoring system. In addition to an incontinence sensor, the system has a temperature sensor. There is disclosure of a remote transmitter and receiver unit for use in the

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system. US-A-5,903,222 describes a garment diaper detector utilising a capacitive sensor. Also disclosed are multiple wetness detectors to monitor a plurality of garments, in a nursing home or hospital, and the transmission of a signal indicating wetness to a central monitoring station, which may be equipped
5 with a modem which communicates the addresses of wet garments to pagers worn by carers.

Documents published since the aforementioned prior art seem to suggest that there has not been much of an advance in incontinence management systems. WO 02/052302 discloses a radio frequency resonant circuit sensing device for
10 the detection of fluid levels, empty containers, and leak of fluids from containers and bodies containing the fluids, in the monitoring of the collection of drain fluid from a person or the leak of fluid from a person suffering from urinary and/or faecal incontinence.

WO 02/078513 describes a patient fluid discharge/position monitoring apparatus
15 and method including an article configured to be worn by a patient, the article having absorbent material and a RF tag adjacent the material. The RF tag is excited by an excitation signal and the response of the RF tag is detected. A first detected response occurs when the absorbent material has no fluid therein, and a second detected response occurs when the material has fluid therein. The
20 detected response is compared to a predetermined response.

Other recent prior art documents relate merely to the treatment of incontinence: US-A-6,110,099, US 2002/0142033 A1, and US 2001/0005728 A1 and related documents. WO 98/12997 discloses a basic pad for detecting *enuresis nocturna*, which pad has a sensor consisting of a conductor printed on non-woven fabric.
25 The pad is limited to the provision of an alarm when *enuresis nocturna* occurs.

It is clear that there is a need for a more sophisticated incontinence management system and apparatus for use with such a system.

It is an object of this invention to provide an incontinence management system

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and/or apparatus which may be used with such a system, either of which is an improvement over the prior art, or at least provides an alternative thereto.

The invention provides a diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body
5 of a person, characterised in that said diaper includes a sleeve for the insertion of a diagnostic strip.

The invention also provides a diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper is provided with a
10 plurality of sensors at different locations in said diaper.

The invention further provides an incontinence management system or a system for the management of other exudates from the body of a person, characterised by an article adapted to be worn by the person, sensing means associated with said article and adapted to sense a condition, and transmitting means adapted to
15 transmit a signal generated by said sensing means to a location.

Embodiments of the invention will be described in detail hereinafter, with reference to the accompanying drawings, in which:-

Fig. 1 is a diagrammatic perspective view of one embodiment of a diaper in accordance with the present invention;

20 Fig. 2 is a diagrammatic perspective view of a second embodiment of a diaper in accordance with the present invention;

Fig. 3 is a front elevation of an embodiment of a sleeve for a diagnostic strip;

Fig. 4 is a rear elevation of an embodiment of a sleeve for a diagnostic strip;

Fig. 5 is a diagrammatic perspective view of a pad for use in an infant's diaper;
25 and

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Fig. 6 is a diagrammatic perspective view of an alternative pad for use in an infant's diaper.

As well as the urinary and faecal incontinence referred to in the introduction to this specification, the present invention is intended to relate to the management,
5 monitoring and treatment of the production of other bodily fluids and exudates from the body of a patient or resident. Such bodily fluids may include cerebro-spinal fluid (CSF), peritoneal fluid, synovial fluid from joints and bursae around joints, and material discharged from wounds.

As has been described in the preamble to this specification, developments in
10 incontinence management systems have largely been restricted to systems in which the status of a patient suffering from urinary, faecal or other incontinence is remotely monitored to ensure compliance with protocols and patient comfort. The present invention, and embodiments thereof, contemplates the broadening of such systems to provide for diagnosis and treatment of conditions which result in
15 incontinence.

An extensive list of clinically relevant medical conditions may be recognised or suspected by the detection of a number of metabolites, chemicals and ions, as well as other substances and cells of different types, in urine. Such materials as
nitrites, amino acids, Beta-2 microglobulin, such measurements as pH,
20 osmolality, white cell count, protein, specific gravity, and such conditions as multiple myeloma and haematuria, may be detected by testing urine from a patient.

The system of the present invention has as its core a diaper to be worn by the patient, which diaper has features which enable it to monitor incontinence,
25 particularly urinary incontinence, by, for example, collecting data from the patient wearing the diaper, and transmitting it to a location where such data may be processed. The diaper may also include features which enable samples of, for example, urine, to be withdrawn *in situ* from such a diaper, for testing.

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Fig. 1 shows a diaper 10 which is adapted to be worn by a patient (not shown). Preferably, the diaper 10 is disposable and/or re-usable, and preferably has an elasticised waistband 12 and elasticised upper thigh bands 14, 16. The diaper 10 is intended to permit the estimation of the volume of urine flowing from the patient in real time. This is effected by the placing of one or more moisture (wetness) sensors 18 at different locations in the diaper 10. The sensors 18 form part of a radio transmitting and data capturing arrangement (not shown), operated by special software.

Preferably, the sensors 18 are constituted by conductive inks, and will detect the presence of moisture. These conductive inks, which are preferably special conductive inks of various formulations, are connected to the aforementioned arrangement, which may be a purpose designed continence management system which captures the data captured by the sensors 18, which data is recorded via radio transmission to hardware running a computer software program. Some of the data may also be transmitted to nursing staff or a nursing station responsible for the management of the incontinence episode in an appropriate manner for the patient or resident in question.

The conductive inks used in the sensors 18 are preferably based on low-cost materials such as carbon, formulated on the carbon content of different concentrations and composition, to achieve the most appropriate sensitivity for moisture detection. Current conductive units are silver-based, and accordingly are too expensive for use in a disposable diaper.

The choice of carbon or a similar inert substance will reduce the likelihood of interference with chemical markers, which may be incorporated into the sensors 18, for the detection of clinically relevant substances of the type referred to earlier in this specification. Information captured by the chemical markers is transmitted using radio or the like technology, and processed by specially designed software, to be used for improved management of clinical conditions of residents and patients by medical or nursing staff.

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Preferably, the conductive ink will be such that rapid drying or curing will be achieved to enable manufacture of disposable diapers 10 to be carried out at rates consistent with the production of existing and future diapers, presently in the order of 400 diapers per second. The manufacturing process may be carried out using ultraviolet light in a manner similar to that used in rapid curing of dental materials for various dental procedures such as dental fillings.

In a preferred arrangement, the volume of urine passed by the resident or patient, preferably in a unit of time, will be established using a mathematical model computed by using such factors as the distance between sensors 18, the rate of transfer of moisture between sensors 18, and the absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres. The information from the sensors 18 is transmitted using existing radio technology, and the data is processed using specially designed software running the aforementioned mathematical model.

The sensors 18 incorporate diagnostic qualities, which differ from the arrangement of Fig. 2, to be described hereinafter, because the system of Fig. 1 does not use blood-derived components.

Turning now to Fig. 2, that figure shows a diaper or the like 20 which may fundamentally be similar to the diaper 10 of Fig. 1, and which is adapted to be worn by a patient or resident suffering from some form of incontinence.

Preferably, the diaper 20 is disposable and/or re-usable, and preferably has an elasticised waistband 22 and elasticised upper thigh bands 24, 26.

The diaper 20 has a sleeve 28 located preferably in the area of the diaper 20 close to the pubic area of the patient or resident. The sleeve 28 is intended to house a diagnostic strip or the like 30. Such diagnostic strips 30 may be of the Multistix/Combistix type or similar to other strips which are able to detect relevant substances in urine, for example blood, sugar, nitrites, leucocytes, urea, specific gravity, protein, and other substances. As some of the chemical sensors on the strips 30 use and are derived from blood products, the sleeve 28 will protect the

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skin of the wearer from such blood derived products and thus accidental infection with hepatitis B, hepatitis C or HIV.

It is considered that as the information to be obtained from the diagnostic strips 30 may need to be obtained within certain time frames, the sleeve 28 will need to
5 allow for a sufficient volume of urine to be captured so that the urine may make contact with the strip 30, and for radio transmission of data to take place within the required time frame.

Figs. 3 and 4 show front and rear views of an exemplary sleeve 28 for a diagnostic strip 30. The sleeve 28 is secured to diaper 20 as will be described
10 hereinafter, and is designed and constructed of materials which will attract and capture urine from the patient or resident. This will expose the chemical sensors on the strip 30 to the collected urine.

The front 32 of the sleeve 28 may be provided with a V-shaped notch 34 for ease of insertion of a diagnostic strip 30. Pores and channels 36 may be provided to
15 facilitate the drawing in of the urine to the interior of the sleeve 28, effectively "sucking up" the urine. The rear 38 of the sleeve 28 may be provided with adhesive material 40 for attaching the sleeve 28 to the diaper 20 or pad, in much the same manner as used in feminine hygiene products.

We have, earlier in this specification, referred to clinically relevant medical
20 conditions which may be recognised in urine samples. A sleeve 28 according to the present invention will allow urine to be captured in sufficient volume to permit the detection of relevant clinical substances. The interpretation of the results of such detection are preferably based upon a recalibration of what may be regarded as normal or abnormal, compared to existing "dipsticks", which have
25 established normal and abnormal values for interpretation. This re-standardising may be required to take account of any alteration which may occur in the components in the urine samples, as a result of the present invention. For example, diaper fibres may trap some white blood cells, so that a new "normal value" may be needed to be established to cater for such a possibility. As a

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consequence, a new lower value for the number of leucocytes in a sample may be required.

Another example relates to the test for the albumen:creatinine ratio in a spot urine sample. A level of 0.7 mg/mmol corresponding to a urinary excretion rate of more
5 than 5 mgm/min would indicate a high-risk (in cardiovascular terms) patient requiring aggressive treatment. This marker of arterial damage may be considered with raised cholesterol and hypertension as a serious risk factor for cardiovascular disease. Such values would be revised if necessary for the purposes of the present invention.

10 The sleeve operates as follows. Urine is drawn into the sleeve 28 via capillary action, osmosis and semipermeable membrane processes, thereby bringing the urine into contact with a diagnostic strip 30, which may be a proprietary strip such as marketed under the Bayer and Roche brands, to enable the "reading" to take place in a timely fashion. The carer or nurse will have been alerted to the
15 availability of the urine sample through the radio-based system and software-based system described earlier in this specification.

Patients or residents may be required to take standard known quantities of substances such as creatinine to carry out reliable, accurate tests which the incontinence management system is able to interpret reliably. Such ingested
20 substances may be excreted in an unmetabolised form, for example, as creatinine asparagine, or may be actively metabolised and measured as a metabolite in the urine.

The embodiment of Figs. 3 and 4 of the present invention makes possible the interpretations of findings in near real time, as the requirement of testing fresh,
25 recently passed, urine is essential for the most accurate interpretations to take place.

In Fig. 5 there is shown a pad 42 which preferably is adapted to be attached to a diaper (not shown) of a neonate, baby or a child, more preferably by adhesive means such as 44. The pad 42 itself is preferably formed from an absorbent

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material 46 such as a sponge or sponge-like material, to take up urine excreted by the baby. The pad 42 may also preferably be fitted with a transmitter 48 for transmitting data to the system(s) described previously in this specification. One example of such a signal would be a signal representative of the fact that voiding
5 had taken place. This may be accomplished by linking the transmitter 48 with a wetness sensor (not shown).

Currently, there are three existing sample collection methods, where the collection samples are carried out by "catch" techniques, adhesive collection bags, or suprapubic bladder puncture. There are also "time interval" tests, such
10 as 1-hour and 2-hour tests to establish levels of incontinence during the stated time intervals, in which conventional pads are simply weighed to determine the volume of urine. These are termed "pad tests".

The pad 42 shown in Fig. 5 is much more sophisticated. It preferably comes in three versions. The first version would be a "wetness only" signalling pad, where
15 a parent or nurse would be alerted in real time of passage of urine, would collect the pad and place it in a suitable container to be sent promptly to the microbiology and pathology lab for testing, or would draw up the urine via a syringe for placement in a container, with the container being sent to the lab.

The second type involves the pad 42 having a collecting chamber (not shown)
20 incorporated therein, into which urine has been drawn. This chamber is preferably removable, so that it may be removed when a predetermined amount of urine, or urine passed in a predetermined period of time has been passed, and sent to the microbial/pathology lab.

The third type of pad 42 would have a chamber such as that described in relation
25 to the second type, but which would include diagnostic strips of the type and purpose described hereinbefore in relation to Figs. 2 to 4. The design of the collection chamber, sleeve or pocket will be such that it will collect urine for dipstick testing, for collection of samples to be transported for pathology/bacteriology testing, or *in situ* testing using the new sensors designed
30 for the incontinence management system.

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The collection chamber, sleeve or pocket will be designed in conjunction with the diaper to which it is attached, which diaper draws and feeds the urine into the chamber, to maximise the volume of urine collected, when only small voids have occurred.

- 5 Alternatively, urine may be expunged from a urine-soaked pad 42 via a special container which may expel urine by the use of a plunger (not shown), which may be compared to the plunger in a coffee plunger, which is able to force urine into a sealed compartment (not shown), separate from the pad 42.

10 The pad 42 may have capillary channels (not shown, but preferably similar to channels 36 of Fig. 3, to draw the urine towards the collection chamber. The pad 42 and/or diaper containing the pad 42 may also preferably use materials designed for osmosis, capillary action or other manner of providing directional flow of urine to assist in the transfer of the urine to a location where it is required.

15 Fig. 6 shows an alternative pad 50, which may be generally similar to pad 42 of Fig. 5, but which has a generally cylindrical shape.

Reference is now made to the extension of the present invention to other bodily fluids and exudates from the body of a person. In the case, for example, of serous and other exudates, a dressing for a wound are preferably provided such that information about the wound may be relayed via sensors located on or in
20 association with the dressing, which would otherwise be difficult to determined because conventional dressings or casts would be in the way.

It may also be the intention of the present invention to provide sensors of the dipstick and/or electronic type for dressings on wounds. Additional components, ions and chemical markers of bodily fluids or exudates from the body, may be
25 detected *in situ* or via the sensors located on or in association with the sensors. Presently, such body products are tested away from the patient in biochemical and bacteriological laboratories. The sensor-equipped dressings may also be used to inform nursing staff of ooze, and content.

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The entire contents of the provisional specification (description and drawings) of Australian provisional patent application no. 2004906315, filed on 3 November 2004, are hereby incorporated into this specification.

The claims form part of the disclosure of this specification.

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CLAIMS

1. A diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper includes a sleeve for the insertion of a diagnostic strip.
- 5 2. A diaper according to claim 1, characterised in that said sleeve is located on said diaper close to, in use, the pubic area of a wearer.
3. A diaper according to claim 1 or claim 2, characterised in that said diaper has means designed to direct fluids excreted by said person, to said sleeve.
- 10 4. A diaper according to any preceding claim, characterised in that said sleeve is provided with a V-shaped notch to facilitate the insertion of a diagnostic strip.
5. A diaper according to any preceding claim, characterised in that said sleeve is attachable to said diaper by adhesive material.
- 15 6. A diaper according to any one of claims 3 to 5, characterised in that said means designed to direct fluids excreted by said person, to said sleeve, is constituted by pores and/or channels.
7. A diaper according to claim 6, characterised in that said pores and/or channels are located around the periphery of said sleeve.
- 20 8. A diaper according to any preceding claim, characterised in that sleeve is adapted to retain a predetermined amount of exudate to facilitate contact of said exudate with said strip.
9. A diaper for a person to wear, for use in an incontinence management system or a system for the management of exudates from the body of a

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person, characterised in that said diaper is provided with a plurality of sensors at different locations in said diaper.

10. A diaper according to claim 9, characterised in that said sensors are wetness sensors.
- 5 11. A diaper according to claim 10, characterised in that said sensors are adapted to permit the estimation of the volume of exudate flowing from the patient in real time.
12. A diaper according to claim 11, characterised in that the volume of exudate passed by the person wearing said diaper, preferably in a unit of time, is

10 established using a mathematical model computed by using such factors as the distance between said sensors, the rate of transfer of moisture between said sensors, and the absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres.
- 15 13. A diaper according to any one of claims 9 to 12, characterised in that data from said sensors is transmitted using radio technology, and in that said data is processed using software running the aforementioned mathematical model.
- 20 14. A diaper according to any one of claims 9 to 13, characterised in that each of said sensors is constituted by conductive inks.
- 15 15. A diaper according to any one of claims 9 to 14, characterised in that the spacing of said sensors is at different thicknesses in material forming at least a part of said diaper.
- 25 16. A pad for use with a diaper, said pad being associated with transmitting means, for transmitting signals representative of an aspect of fluids absorbed by said pad, to a remote location.

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17. A diaper according to claim 16, characterised in that said pad includes a chamber for collection of said fluids.
18. A diaper according to claim 17, characterised in that said chamber is removable.
- 5 19. An incontinence management system or a system for the management of other exudates from the body of a person, characterised by an article adapted to be worn by the person, sensing means associated with said article and adapted to sense a condition, and transmitting means adapted to transmit a signal generated by said sensing means to a location.
- 10 20. An incontinence management system according to claim 19, characterised in that said system also includes means for processing said signal.
21. An incontinence management system according to claim 19 or claim 20, characterised in that said sensing means is a plurality of sensors, arranged spatially in said article.
- 15 22. An incontinence management system according to claim 21, characterised in that said special arrangement includes the spacing of sensors at different thicknesses in material forming at least a part of said article.
23. An incontinence management system according to any one of claims 19 to 22, characterised in that said article is a diaper.

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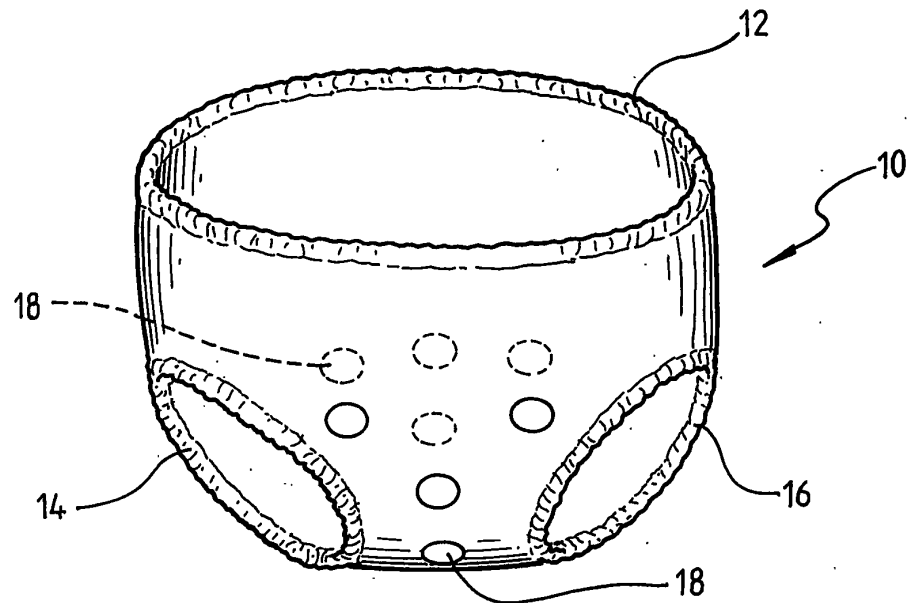


Fig. 1

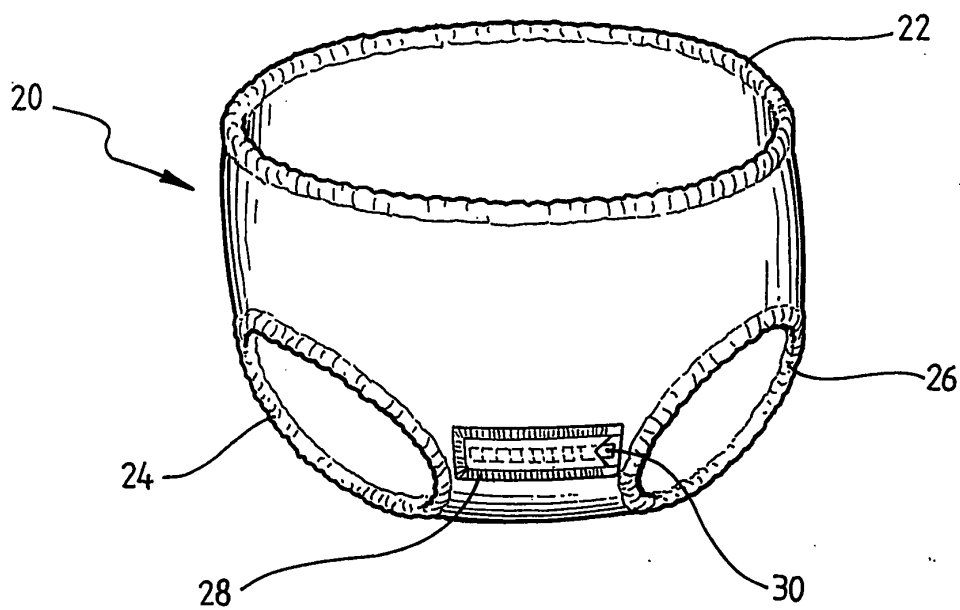


Fig. 2

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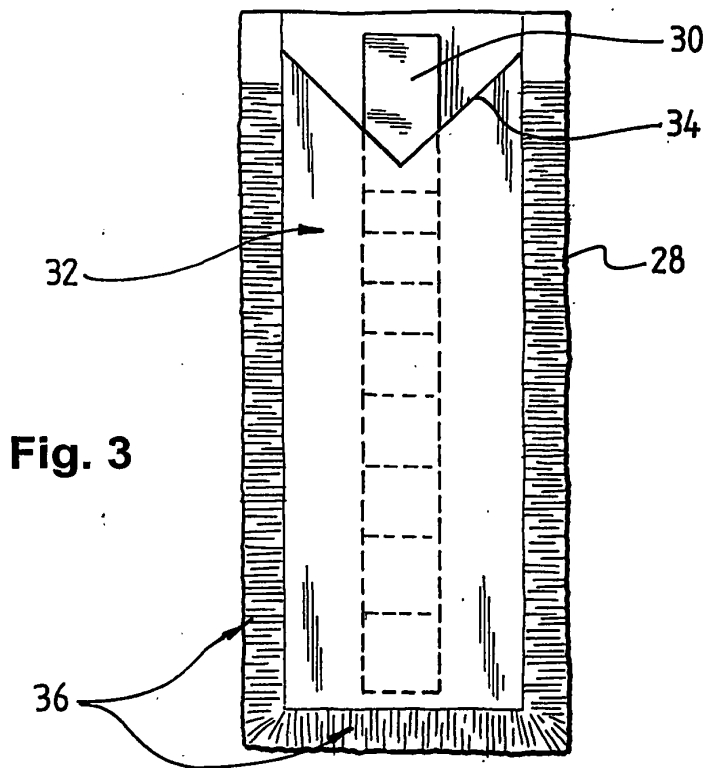


Fig. 3

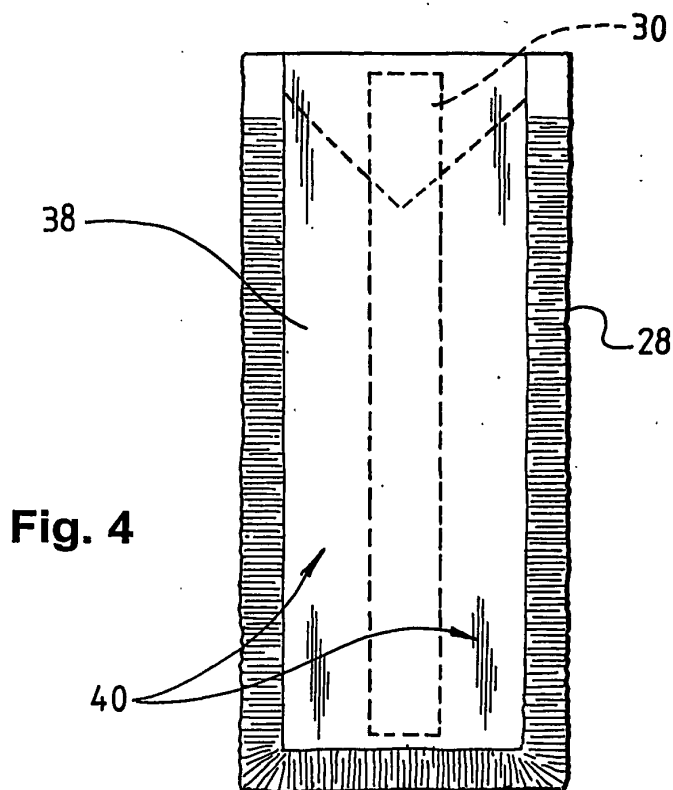


Fig. 4

SUBSTITUTE SHEET (RULE 26) DRAWING

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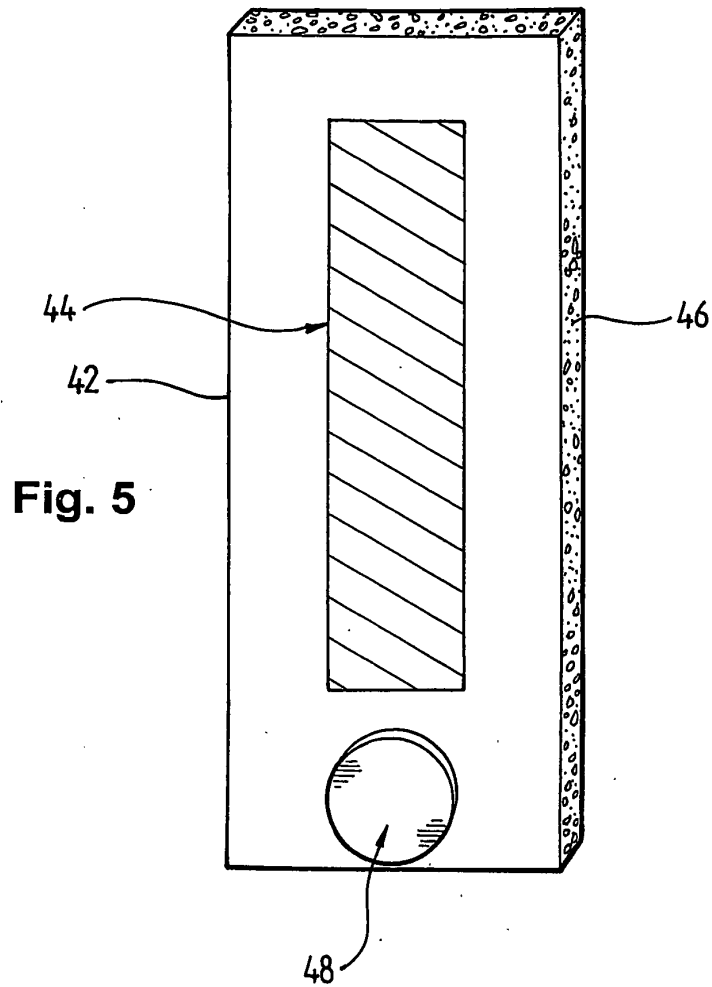
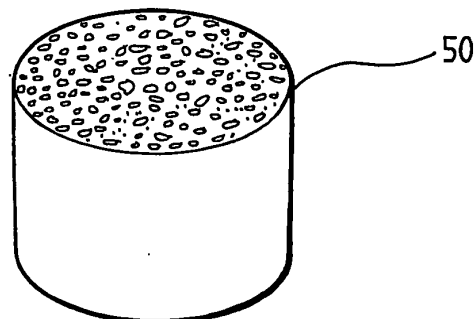


Fig. 6



INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER		
Int. Cl. ⁷ : A61F 13/42		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols)		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI IPC A61F +keywords (incontinence, diaper, sleeve, pocket, strip, sensor, insert, wet, enuresis and similar terms)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR 2733146 A1 (CARRIEL) 25 October 1996 Pages 4-9	1-3, 5
X	US 5902296 A (FLUYERAS) 11 May 1999 Columns 1-4	1, 2, 5
X	US 4507121 A (LEUNG) 26 March 1985 Figure 1, columns 2 and 3	1-3, 6
A	DE 19837678 A1 (STRECKERT et al) 2 March 2000 Whole document	
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
<p>* Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
Date of the actual completion of the international search 21 November 2005		Date of mailing of the international search report 2 - DEC 2005
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929		Authorized officer Sue Thomas Telephone No : (02) 6283 2454

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2005/001667

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:1-8

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2005/001667

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-8. It is considered that a sleeve for the insertion of a diagnostic strip comprises a first "special technical feature".
2. Claims 9-15. It is considered that a plurality of sensors at different locations comprises a second "special technical feature".
3. Claims 16-18. It is considered that associated transmitting means for transmitting signals representative of an aspect of fluids absorbed to a remote location comprises a third "special technical feature".

Since the abovementioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

It is considered that search and examination for each of the second and third inventions will require more than a little additional search and examination effort over that for the other inventions, and therefore two additional search fees are warranted.

4. Claims 19-23. It is considered that the "special technical features" of these claims, sensing means adapted to sense a condition and transmitting means adapted to transmit a signal generated by said sensing means to a location are related to groups 2 and 3 and could be searched with little extra effort requiring no extra fee if both groups 2 and 3 were to be searched.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2005/001667

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member
DE	19837678	NIL
FR	2733146	NIL
US	5902296	NIL
US	4507121	NIL

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

END OF ANNEX

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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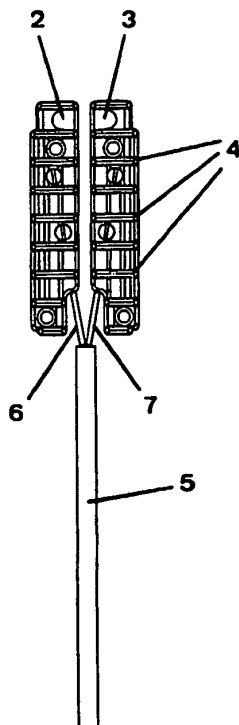
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[Continued on next page]

(54) Title: DEVICE AND APPARATUS FOR DETECTING MOISTURE



(57) Abstract: A device for detecting the presence of bodily fluid, the device including a detector (1) means having two spaced apart electrodes (2, 3), each electrode is connected to a signal generating means via a lead (6, 7). The electrodes are encased in a flexible non-conductive material with each including at least one protruding conductive element (4). The protruding elements are separated by the same distance as the spacing between the two electrodes. The device also includes a signal processing means that detects a change of state across the electrodes produced by the introduction of a fluid and an alarm actuated by the change of state.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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DEVICE AND APPARATUS FOR DETECTING MOISTURE

TECHNICAL FIELD

5 This invention relates to a device and apparatus for detecting and monitoring bodily fluids. More particularly, but not exclusively, the invention relates to a device and apparatus for detecting urine and/or blood and/or excessive perspiration and generating an alert signal in response to such detection.

10 BACKGROUND ART

The early detection of bodily fluids in some situations can be important to the well being of a person. For example, the early detection of any leakage of blood around the site of insertion of a dialysing needle during dialysis treatment, and in particular nocturnal dialysis, may be
15 useful. The detection of other bodily fluids such as perspiration, particularly high levels of perspiration indicating hypoglycaemia in insulin-dependent diabetics, may be important for the wellbeing and care of that person.

Sufferers of enuresis, particularly in relation to nocturnal enuresis causing bedwetting, or
20 diurnal wetting, can be assisted by the use of a detector and alarm unit that serves to wake the person when the presence of urine is detected. A number of disadvantages with many types of devices is that they can be too small to detect the presence of bodily fluid or they can be too large and cause discomfort for the wearer. Many are made from metal, printed circuit board material or other solid and rigid materials that can cause discomfort to the extent of
25 causing significant irritation if they are in contact with the skin of the wearer. Further, some of these detecting devices are typically not durable or robust and need to be replaced after a short period of use.

It is a non-limiting object of the invention to provide a device for detecting bodily fluid which
30 overcomes at least some of the abovementioned problems, or at least to provide the public with a useful choice.

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It is a further non-limiting object of the invention to provide an apparatus for detecting bodily fluid and generating an alarm signal which overcomes at least some of the abovementioned problems, or at least to provide the public with a useful choice.

5

SUMMARY OF THE INVENTION

According to a first aspect of the invention there is provided a device for detecting the presence of bodily fluid, the device including a detector means including at least two spaced
10 apart electrodes defining an open electrical bridge and each electrode being electrically connectable to a signal generating means via a wire, the electrodes being configured and arranged, in use, to provide a path for electricity to conduct across a predetermined distance or gap between the electrodes when a sufficient amount of bodily fluid bridges the distance or gap between the electrodes, and wherein the conductive electrodes are substantially encased
15 in a flexible non-conductive material with each conductive electrode including at least one protruding conductive element separated by the predetermined distance or gap between the electrodes.

Preferably the conductive electrodes are overmoulded with a suitable flexible non-conductive
20 thermoplastics material. Desirably the thermoplastics material is a flexible thermoplastic silicone vulcanizate material. Advantageously each said conductive electrode includes nine protruding conductive elements separated by the predetermined distance or gap between the electrodes.

25 Preferably the pair of conductive electrodes are configured and arranged with nine protruding conductive elements formed in each said electrode, the conductive elements being exposed through the overmoulded non-conductive thermoplastics material, and wherein the nine opposing conductive elements are aligned along the length of the detector means with the predetermined distance or gap between each opposing pair of conductive elements.

30

Preferably the wire is adapted to be releasably connectable to the signal processing means.

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According to a second aspect of the invention there is provided a moisture detection apparatus including the device of claim 1, and including a signal processing means configured and arranged to detect a change of state across the electrodes and actuate an alarm
5 means, and a power source means for powering the signal processing means and the alarm means.

Preferably the signal processing means and the alarm means are configured and arranged within a housing, and wherein the detector means is located remotely from the housing and
10 connected via the wire to a removably attachable connector means to the input of the signal processing means.

Desirably the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to generate a suitable input signal to an audible alarm means
15 so as to actuate an audible alarm in response to the detection of bodily fluid by the detector means.

Preferably the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to prevent current from flowing through the detecting device
20 once the alarm means is activated. Desirably the alarm is a piezoelectric ceramic speaker.

Alternatively the signal processing means includes a transmitter means that receives a suitable input signal and transmits an output signal to a receiver means, and wherein the receiver means receiving a signal from the transmitter means to actuate an audible alarm
25 means in response to the detection of bodily fluid by the detector means.

Preferably the power source means is a battery supplying a nominal six volt direct current supply.

30 Optionally the bodily fluid being detected is urine and/or blood and/or excessive perspiration.

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BRIEF DESCRIPTION OF THE DRAWINGS

5 Preferred embodiments of the invention will now be illustrated, by way of example only, with reference to the accompanying drawings in which:

Figure 1: Shows a side view of the electrodes and cable connected thereto before an overmoulding process;

10

Figure 2: Shows a perspective view of figure 1;

Figure 3: Shows a side view of the overmoulded electrodes and cable of a device 1 in accordance with one preferred embodiment of the invention;

15

Figure 4: Shows an end view of figure 3;

Figure 5: Shows a perspective view of figure 3;

20

Figure 6: Shows a schematic block diagram of main components of a moisture detecting apparatus 10 according to one preferred embodiment of the invention;

25 **Figure 7:** Shows a circuit diagram of the moisture detecting apparatus 10; and

Figure 8: Shows a schematic block diagram of main components of a moisture detecting apparatus 20 according to a second preferred embodiment of the invention.

30

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DETAILED DESCRIPTION OF THE DRAWINGS

Referring to figures 1 to 5, a moisture detection device, generally referred to as 1, according to one preferred embodiment of the invention, is illustrated.

5

The moisture detection device 1 of the invention has been designed to provide increased comfort to users by being substantially flexible and by having properties making it relatively durable and resilient.

- 10 In this description references are made to the detection of bodily fluid and/or moisture, and in the case of a bodily fluid it can include urine, blood and/or perspiration/sweat depending on the application of the invention. For ease of reference to these terms the following description will mainly refer to moisture, although it will be appreciated that the device 1 of the invention can detect a variety of bodily fluids.

15

- The device 1 for detecting the presence of moisture includes a detecting means including at least two electrically conductive moulded electrodes 2, 3 in a spaced apart arrangement. The spaced apart arrangement is to define an open circuit bridge. The electrodes 2,3 are made of any suitable durable and resilient and conductive material, and are preferably made of a
- 20 conductive polymer. More preferably the electrodes 2,3 are formed of a un-plastisized conductive polyvinyl chloride ("PVC"), and including a filler of carbon black particles providing the conductive properties of the electrodes 2,3.

- The electrodes preferably include raised or protruding conductive elements 4 aligned along
- 25 each electrode 2,3. As seen in figures 1 to 5, there are nine spaced apart protruding conductive elements 4 moulded along the length of each electrode 2,3. The electrodes 2,3 are advantageously aligned such that there are seen to be nine pairs of opposing conductive elements 4 with a predetermined distance or gap X between respective elements 4 in each electrode 2,3. The gap X can be any suitable distance and is substantially between about 2 to
- 30 5 millimetres in this embodiment. An advantage with this arrangement is that, when in use, moisture can be detected between any opposing pair of elements 4 and therefore the detector

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means can be considered to offer a detection device 1 that is relatively sensitive in detecting the presence of moisture.

The electrodes 2,3 are adapted to allow wires 6,7 of an electrical cable 5 to be fastened or
5 connected to respective electrodes 2,3. As seen in figures 3 and 4, the electrodes 2, 3 are advantageously encased in a suitable durable and resilient and flexible non-conductive material 8, and in this embodiment of the invention they are preferably encased in a flexible non-conductive thermoplastics material 8. More desirably, the electrodes 2,3 are overmoulded in a non-conductive alloy type thermoplastic elastomer based on vulcanized
10 silicone rubber particles in a thermoplastic matrix. One such example that can be applied to the device 1 is a thermoplastic silicone vulcanizate with a hardness of substantially about 50 shore A offering good tensile property retention and durability and hydrolytic resistance making such material particularly suitable in the device 1.

15 As seen in figures 3 to 5, the non conductive overmoulded material 8 is advantageously shaped as an elongate paddle over the elongate electrodes 2,3 and forms a flexible and durable neck 9 at the base of the paddle. The neck 9 also moulds to the outer sheath of the cable 5.

20 The cable 5 in this non limiting embodiment is a two wire 6,7 stranded cable of 0.75mm² with a PVC jacket. The length of the cable 5 in one non-limiting application is any suitable and desirable length required between the detector and the alarm means, and can be about 80cm to a metre for many applications. The other end of the cable is terminated or connected to a plug adapted to insert into a suitable socket in the input to the signal processing means as
25 detailed below.

As seen more clearly with reference to figure 4 showing an end view of the device 1, the end portions of the conductive elements 4, seen as conductive strips, protrude through the top surface of the overmoulded material 8. These protruding elements 4 are effectively the
30 contact terminals of the electrical bridge between electrodes 2,3. The device 1 has been designed to offer substantial flexibility as the device 1 can be twisted and manipulated into

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position and can be flexed during operation without splitting or breaking the device 1. Further, as the overmoulding substantially encases the electrodes 2,3 and exposed wires 6,7 making it substantially water impervious, the device 1 can be repeatedly washed, even in hot water, and reused which is desirable for hygienic given its use in blood or urine drenched applications.

The paddle device 1 is seen to be relatively thin and flexible, and is about 40 millimetres long and 20 millimetres wide, and about 3.5 millimetres in thickness. The overall dimensions of the device 1 are to allow it to function well enough to detect moisture, and be small enough to be comfortable for use by a person. However, one of the main benefits of a soft and flexible paddle shaped detection device 1 is that it can be easily inserted into place and can provide a level of comfort for users.

Referring now to figures 6 and 7, schematic and circuit diagrams of a moisture detecting apparatus, generally referred to as 10, according to one preferred embodiment of the invention, is illustrated.

The moisture detection apparatus 10 of the invention, in one non-limiting application, is designed to assist an enuresis sufferer to develop an increased sensitivity to subliminal bladder contractions and ultimately may allow a user to learn to inhibit the reflex to pass urine, particularly when asleep.

The apparatus 10 preferably includes the moisture detection device 1 as described with reference to figures 1 to 5. The cable 5 extending at one end of the device 1 is of any suitable and desirable length and can desirably include a plug connector 11 terminated at the other end of the cable 5. The plug 11 may be a mono plug, and the signal processing means 13 is adapted with a suitable connector or socket 12 for releasably receiving the plug 11 for operational purposes and for resetting the apparatus 10.

The apparatus 10 is broadly divided into main components as shown in figure 6. The sensing device 1 is electrically connected via the plug 11 to the socket 12 in a printed circuit board of

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the signal processing means 13. A power source means 14 preferably in the form of a battery comprising four button sized 1.5 volt cells supply about 6 volts direct current to the apparatus 10. The signal processing means 13 is configured and arranged with a plurality of suitable electrical circuit elements to monitor the output and state of the moisture detecting device 1
 5 and to generate and process a signal suitable for feeding to the alarm indicator means 15. The alarm indicator means 15 may include any form of alert means including but not limited to an audible alarm and/or a visual display means such as, for example, a flashing light emitting diode or array of diodes (not shown) or other such indicator means to alert either a person using the apparatus 10 or a nurse or doctor or otherwise monitoring the person or patient.

10

The electrical circuit broadly represented as the signal processing means 13, the power source means 14 and the alarm indicator means 15 are desirably arranged in a compact and durable and resilient housing or casing 16. It is envisaged that the casing 16 will be as thin, lightweight and compact as possible to allow the circuitry to be protected and function
 15 effectively and also provide a level of comfort for users. The casing 16 can advantageously be of a size approximating about 50 millimetres in length and about 40 millimetres in width and about 15 millimetres in thickness.

In this embodiment an audible alarm means is used as the alert indicator means 15 and
 20 further details of the operation of the apparatus 10 is explained with reference to the circuit diagram illustrated in figure 7. It will be appreciated that this electrical circuit is supplied as one non-limiting example of the operation of the invention.

Referring now also to figure 7, the operation of the apparatus 10 is broadly noted as follows.
 25 To power up the apparatus 10, the plug 11 of the cable 5 is inserted into the socket 12 that is mounted to the PCB and electrically connected to the signal processing means 13. This action connects a 6 volt DC power from the power source means in the form of a battery circuit 14 to the signal processing means 13. The battery circuit 14 desirably includes a filter circuit with a capacitor C3 and a resistor R6 ensuring a smoother power supply to the main
 30 circuitry.

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The device 1 is generally connected in an open circuit state such that it is dry across the outer surface 8 of the paddle with a high resistance between the conductive elements 4. The capacitor C2 ensures that the main circuit powers up in the correct state when power is supplied. The capacitor C2 will initially discharge to ensure that input PIN 12 of NAND gate U1C is at logic 0 which results in the output PIN 11 of gate U1C to be logic 1, and in turn the input to NAND gate U1D to be logic 0. Positive feedback through resistor R3 further keeps the circuit in this state. Capacitor C2 will be charged through resistor R5 such that PIN 12 of gate U1C will be at logic 1.

10 The device 1 is connected through the cable 5 to the resistor R3 to form a potential divider, and a variable voltage depending on the relative resistance at PIN 13 of gate U1C. When the conductive elements 4 are bridged by moisture, the resistance drops across the elements 4 and electrodes 2,3 such that the voltage will rise across PIN 13 of gate U1C and cross the threshold of gate U1C. At this instant, both inputs to gate U1C with PIN 12 and PIN 13 will
15 be at logic 1 and the output of gate U1C will change to logic 0 resulting in both inputs to gate U1D being at logic 0 resulting in the output of gate U1D changing to logic 1 and positive feedback through resistor R3 will ensure this state remains the same until reset.

The present invention offers the additional feature of effectively isolating the electrodes 2, 3
20 of the device 1 once moisture has been detected and the main circuit has been triggered. This is achieved in this circuit by the fact that once the output of gate U1D changes to logic 1 and positive feedback through resistor R3 ensure this state remains the same, the voltage drop across the electrodes 2, 3 is reduced to 0 volts. Because the voltage across the electrodes 2, 3 and the resistor R3 are at the same voltage, there can not be any current flow across the
25 electrodes 2, 3 and therefore effectively the device 1 is isolated. This effect is desirable in applications whereby the device 1 is being used to detect urine as electrical current can cause urine to become acidic through electrolysis, with a risk of skin irritation.

As the output of gate U1D has changed to logic 1, the alarm means in the form of a piezo-
30 electric ceramic speaker BZ1 is actuated and starts beeping to alert a user to the presence of moisture. It is seen that integrated circuit U1B generates a high frequency tone at about 3.7

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kHz that is modulated on/off by operation of modulator U1A and diode D3 at a rate of about 4Hz. The modulation frequency is set by operation of capacitor C1 and resistor R2. The frequency of the speaker BZ1 is set by operation of capacitor C4 and resistors R8 and R9 and whereby the frequency and hence the volume of the speaker BZ1 can be tuned by adjusting
 5 R8 for the desired output.

Optionally if a continuous tone is required rather than an intermittent or beeping tone the on/off modulation effect can be disabled by bridging or connecting across pins TP5 and TP6 to short out capacitor C1.

10

It is seen that the output of the signal processing means 13 is buffered by the alarm indicator means 15 by operation of transistors Q1 and Q2 before driving the speaker BZ1. A bridge circuit is formed by operation of the circuit elements Q1, Q2, R11 and R13 resulting in a drive signal fed to the speaker BZ1 that is almost double the supply voltage of 6 volts.

15

It is seen that the speaker BZ1 will continue to emit a tone until the cable 5 is unplugged from the socket 12 which causes the circuit to be turned off.

The apparatus 10 is considered to be particularly suitable for use by enuresis sufferers. As
 20 the casing 16 is quite compact, it can adapted to be attached to a user's clothing by any suitable fastening means. In the case of problems with enuresis sufferers who are sleeping, suitable attachment means for attaching the casing 16 housing the main circuitry can be provided so that the casing unit 16 is attached close to the head of the wearer.

25 In one application of the apparatus 10 for an enuresis sufferer, the casing 16 part of the apparatus 10 can be attached to the shoulder or associated clothing of a wearer such that the alarm indicator means 15 is mounted close to the wearer's head. The cable 5 can be plugged into the socket 12 and the device 1 can then be positioned inside his or her pants in a suitable position to detect the presence of urine when the user passes urine. It is seen then that when
 30 urine closes the electrical bridge between at least any one respective pair of elements 4 between electrodes 2,3 the alarm indicator means 15 will be is activated and the sleeping

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person should wake up and be made conscious of the fact that they are passing urine. It is seen then that the alarm advantageously functions as a stimulus to assist in bladder training by the person wearing the apparatus 10 of the invention. Once activated the user may remove the plug 11 from the socket 12 and later reinsert the plug 11 to reset the apparatus 10.

5

It is further considered that the apparatus 10 of the invention may also be useful for applications such as the detection of blood leaking around the site of insertion of a needle during dialysis, particularly during nocturnal dialysis. Further, high levels of perspiration may be detected for persons suffering hypoglycaemia in insulin dependent diabetics.

10

Referring now to figure 8, a schematic block diagram of main components of a moisture detecting apparatus 20, according to a second preferred embodiment of the invention, is illustrated. In this embodiment the device 1 is close to the signal processing means and the alarm means can be placed remote from the device 1 by a user or by another person

15 reasonably close that is monitoring the person wearing the sensing device 1.

In this apparatus 20, the cable 5 from the moisture sensing device 1 is connected to terminals of a signal processing means 21. The signal processing means 21 also includes a transmitter 22. The transmitter 22, once activated when the signal processing means detects and
20 processes a positive signal from the device 1, transmits a suitable signal to a receiver means 23 that is fed to a control means 24 that is adapted to trigger an alarm indicator means 25. Many aspects and principles of this electrical circuit and associated elements can be similar to the apparatus 10 as already described and will not be repeated.

25 One method of operation is broadly described as follows. The signal processing means 21 is configured and arranged to monitor the resistance across the electrodes 2, 3 of the device 1. A suitable power supply means in the form of a battery is provided along with a suitable on/off switch. When the resistance drops below a predetermined threshold level because urine has formed a conductive path across elements 4 between electrodes 2,3, the output of an
30 integrated circuit formed as a schmitt trigger changes state such that its output changes to logic 0 and this change of state is sensed by an input to a second integrated circuit (IC), such

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as, for example, an Atmel AT86RF401 IC functioning as a signal processor and radio frequency microtransmitter operating in a band of between about 300 to 450 MHz. When the second IC receives a signal indicating that moisture on the device 1 is present, it starts transmitting at about 750 bps at a low power level of about 1 milliwatt at a frequency of say
 5 about 315.788 MHz. The antenna that is used may be a loop antenna that set in place around the outside of a printed circuit board to which components of the signal processing means 21 and related elements are mounted.

The transmitting signal may be encoded if required, and data that is transmitted may be a 32
 10 bit number unique to the transmitter. The transmitter repeatedly transmits the data to be received by an associated receiver means 23 that is monitoring for transmission of the unique 32 bit number.

The receiver means 23 is also desirably battery powered and includes a suitable radio
 15 frequency receiver (for example a Micrel MICRF009BM IC) and associated circuit elements and RF antenna, signal processing means including a microprocessor controller unit (for example an ATMEL ATTINY12 IC) referred to as a control unit 24, with associated circuit elements, and a suitable alarm indicator means 25.

20 The receiver circuitry can be configured to constantly monitor for the particular 32 bit data that may be transmitted from the transmitter means 22. If the transmitter means 22 is transmitting the 32 bit data once activated by the device 1, the receiver means 23 will receive the signal and feed the signal to the microprocessor control unit 24. The control unit 24 then pulses an oscillator circuit that drives the alarm indicator means 25 in the form of a buzzer or
 25 piezo-electric speaker.

The circuitry at the transmitting side is housed in a suitable compact casing 26. The circuitry at the receiving side is also housed in a suitable compact casing 27.

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It is considered that the alarm means 25 can be conveniently positioned anywhere within the signal receiving range of transmission, and as such can be either close to the user or be remotely monitored by a caregiver or nurse or other person monitoring the user.

- 5 Wherein the foregoing reference has been made to integers or components having known equivalents, then such equivalents are herein incorporated as if individually set forth. Accordingly, it will be appreciated that changes may be made to the above described embodiments of the invention without departing from the principles taught herein.
- 10 It is to be understood that the above description is intended to be illustrative, and not restrictive. Additional advantages of the present invention will become apparent for those skilled in the art after considering the principles in particular form as discussed and illustrated. Thus, it will be understood that the invention is not limited to the particular embodiments described or illustrated, but is intended to cover all alterations or modifications
- 15 which are within the scope of the appended claims.

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CLAIMS:

1. A device for detecting the presence of bodily fluid, the device including a detector means including at least two spaced apart electrodes defining an open electrical bridge and each electrode being electrically connectable to a signal generating means via a wire, the electrodes being configured and arranged, in use, to provide a path for electricity to conduct across a predetermined distance or gap between the electrodes when a sufficient amount of bodily fluid bridges the distance or gap between the electrodes, and wherein the conductive electrodes are substantially encased in a flexible non-conductive material with each conductive electrode including at least one protruding conductive element separated by the predetermined distance or gap between the electrodes.
2. A device according to claim 1 wherein the conductive electrodes are overmoulded with a suitable flexible non-conductive thermoplastics material.
3. A device according to claim 1 wherein the thermoplastics material is a flexible thermoplastic silicone vulcanizate material.
4. A device according to claim 3 wherein each said conductive electrode includes nine protruding conductive elements separated by the predetermined distance or gap between the electrodes.
5. A device according to claim 3 wherein a pair of conductive electrodes are configured and arranged with nine protruding conductive elements formed in each said electrode, the conductive elements being exposed through the overmoulded non-conductive thermoplastics material, and wherein the nine opposing conductive elements are aligned along the length of the detector means with the predetermined distance or gap between each opposing pair of conductive elements.

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6. A device according to claim 1 wherein the wire is adapted to be releasably connectable to the signal processing means.
7. A moisture detection apparatus including the device of claim 1, and including a signal processing means configured and arranged to detect a change of state across the electrodes and actuate an alarm means, and a power source means for powering the signal processing means and the alarm means.
8. An apparatus according to claim 7 wherein the signal processing means and the alarm means are configured and arranged within a housing, and wherein the detector means is located remotely from the housing and connected via the wire to a removably attachable connector means to the input of the signal processing means.
9. An apparatus according to claim 7 wherein the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to generate a suitable input signal to an audible alarm means so as to actuate an audible alarm in response to the detection of bodily fluid by the detector means.
10. An apparatus according to claim 7 wherein the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to prevent current from flowing through the detecting device once the alarm means is activated.
11. A device according to claim 9 wherein the alarm is a piezoelectric ceramic speaker.
12. An apparatus according to claim 7 wherein the signal processing means includes a transmitter means that receives a suitable input signal and transmits an output signal to a receiver means, and wherein the receiver means receiving a signal from the transmitter means to actuate an audible alarm means in response to the detection of bodily fluid by the detector means.

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13. An apparatus according to claim 7 wherein the power source means is a battery supplying a nominal six volt direct current supply.
14. A device according to claim 1 wherein the bodily fluid being detected is urine and/or blood and/or excessive perspiration.
15. A device substantially as herein described with reference to any one of the accompanying drawings.
- 10 16. An apparatus substantially as herein described with reference to any one of the accompanying drawings.

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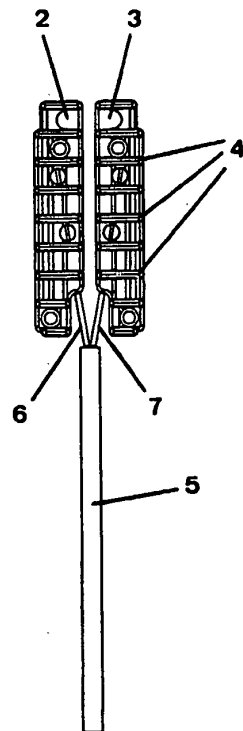


Figure 1

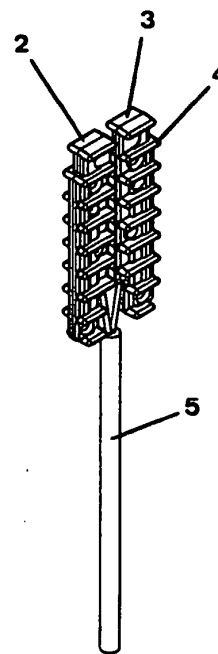


Figure 2

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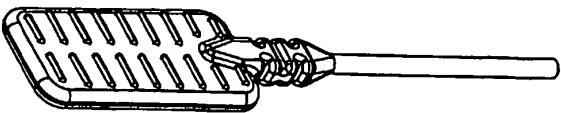


Figure 5

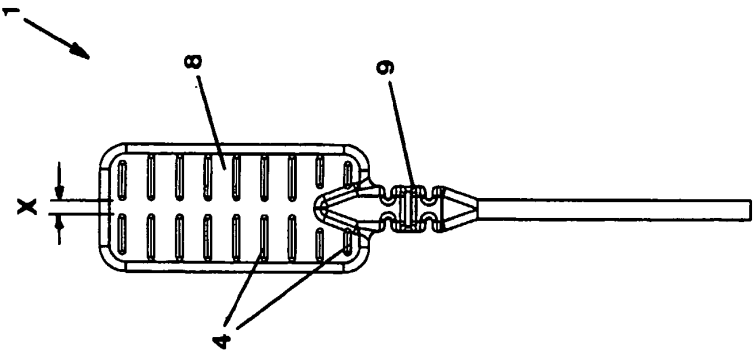


Figure 3

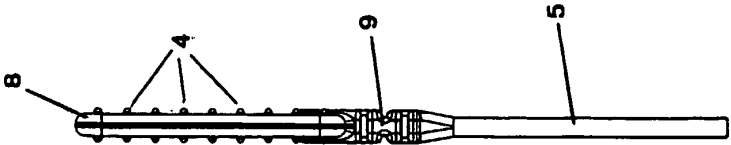


Figure 4

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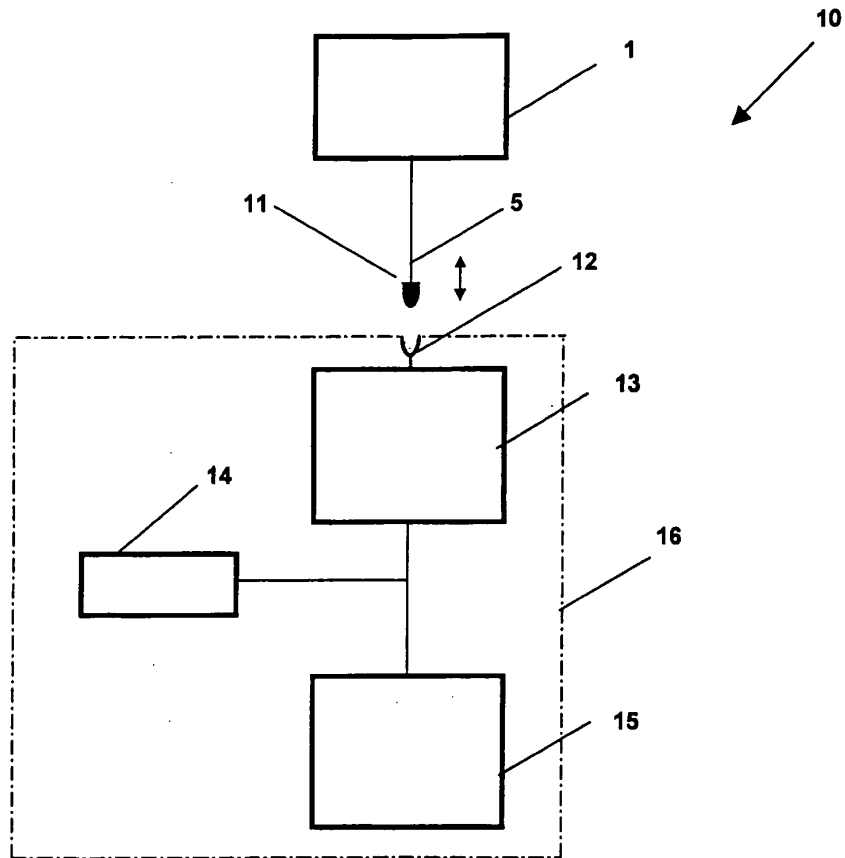


Figure 6

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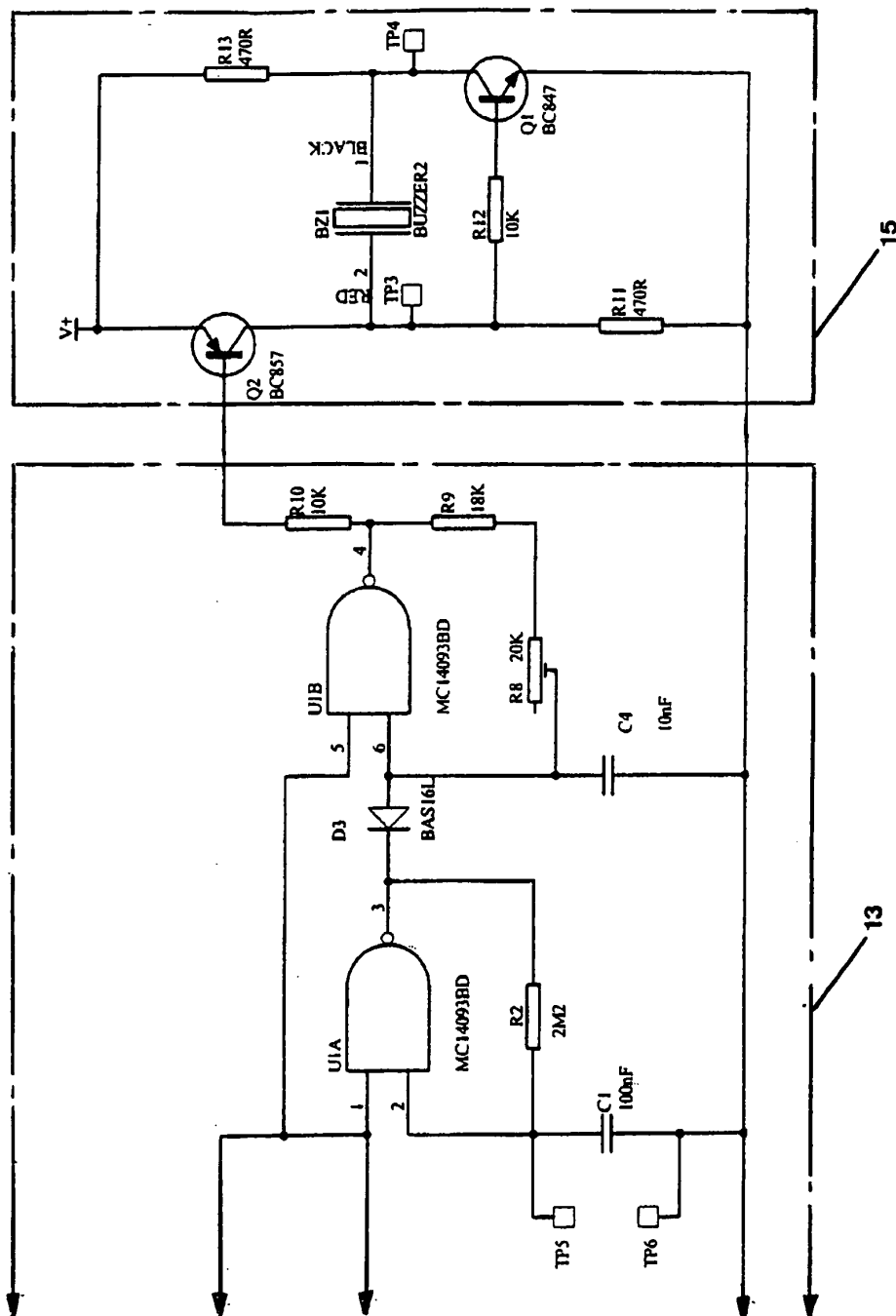


Figure 7

(arrows and circuit diagram continued on sheet 5/6)

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(arrows and circuit diagram follow from sheet 4/6)

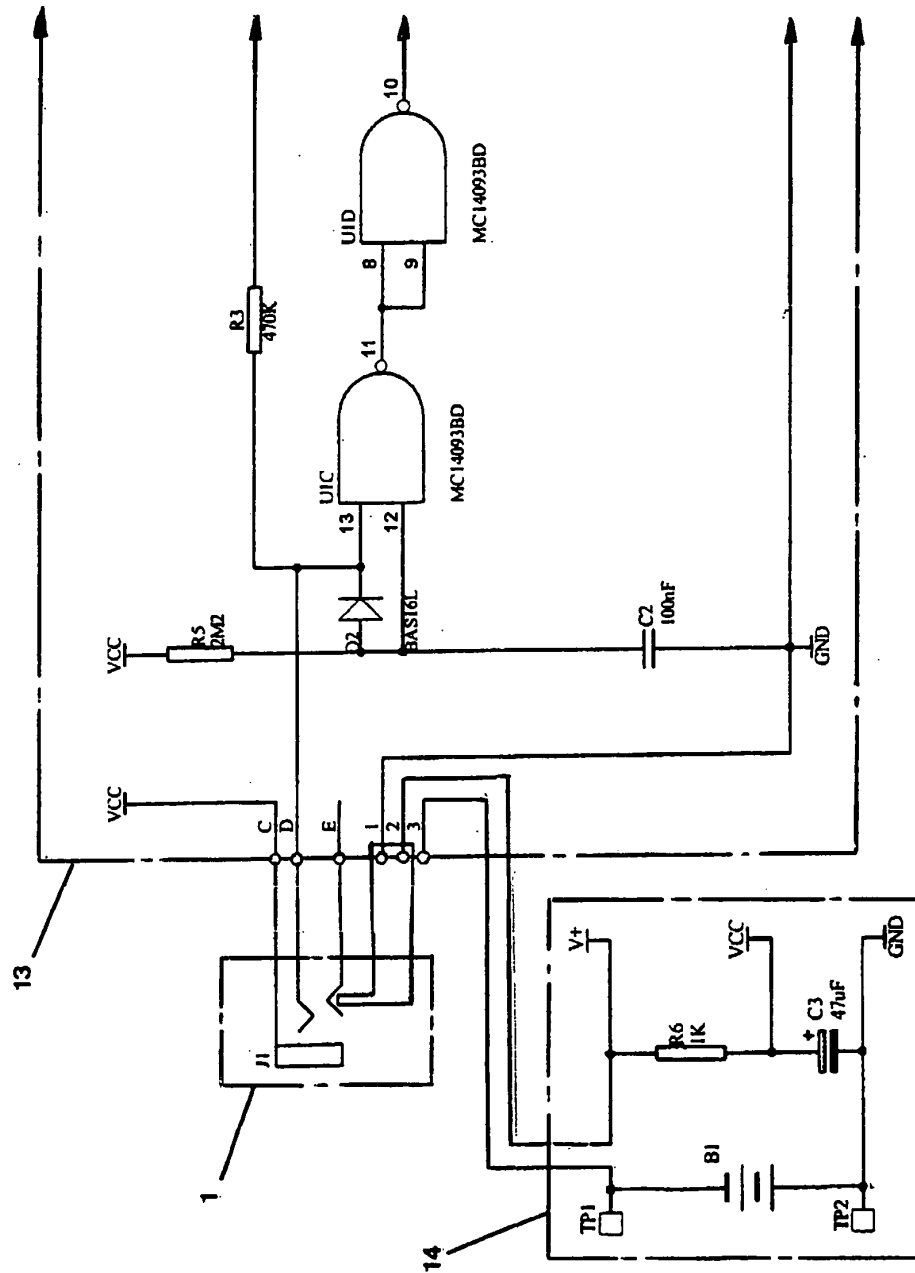


Figure 7

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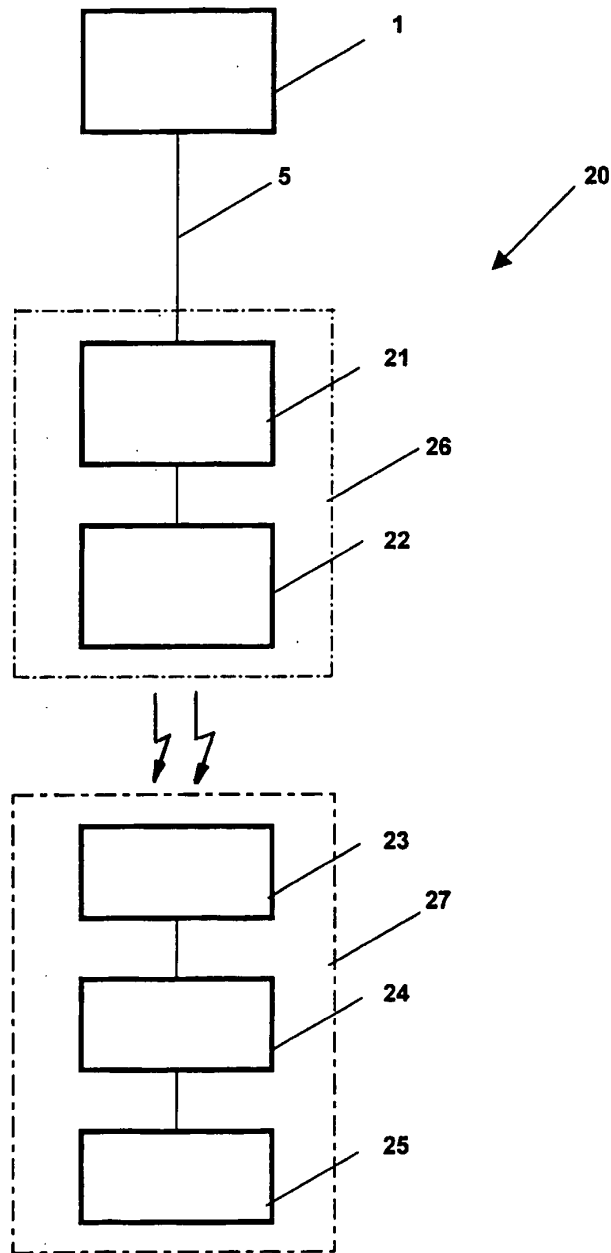


Figure 8

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ2005/000100

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61B 5/00 G08B 21/20 A61F 5/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

ECLA: A61B 5/00E G08B 21/20, 21/20 A61F 5/48 AND KEYWORDS

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI: A61F A61B G08B G01N G01R fluid water blood exudate urine excret faece moist sweat perspiration wet damp electrode lead terminal contact conduct electric detect sense monitor determine indicate measure discover note observe diabet enuresis bed hypogl alarm sound siren audio audit buzz warn alert protrusion projection lump lump lug bump ridge raise space gap separate encase seal enclose

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relévant to claim No.
X	WO 1981000045 A1 (DIA-MED, INC.) 22 January 1981 Page 3 line 35 to page 4 line 18, figures	1-3,7,9,11,13-16
Y		8, 12
Y	US 4374379 A (DENNISON) 15 February 1983 Entire document	1-3,6-16
X	DE 3823859 A1 (KELLERBERG) 18 January 1990 Column 2 line 60 to column 4 line 4, figures	1-3,7,9,11,13-16
Y		8, 12
X	WO 1999063497 A1.(KIMSEY) 9 December 1999 Entire document	1-3,6-16

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents:

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

29 August 2005

Date of mailing of the international search report

02 SEP 2005

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INTERNATIONAL SEARCH REPORT

International application No.

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y Y	US 5557263 A (FISHER et al) 17 September 1996 Entire document	8, 12 1-3, 6-16
Y Y	US 6097297 A (FARD) 1 August 2000 Column 7 line 61 to column 8 line 49, figure 1	8, 12 1-3, 6-16
A	GB 1192421 A (COHEN) 20 May 1970 Entire document	
A	US 4191950 A (LEVIN et al) 4 March 1980 Column 4 lines 37 to 56	
A	US 4977906 A (DI SCIPIO) 18 December 1990 Figure 2, column 5	
A	US 5291181 A (DEPONTE) 1 March 1994 Figures	
A	GB 2272093 A (SMITHS INDUSTRIES PLC) 4 May 1994 Entire document	
A	US 6480731 B1 (DELUCA et al) 12 November 2002 Figures 16 and 17	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/NZ2005/000100

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
WO	8100045	EP	0031841
US	4374379	US	4365637
DE	3823859		
WO	9963497	AU	42742/99
US	5557263	EP	1082711
		US	6373395
		AU	47882/93
		EP	0663097
		US	5790036
		WO	9402918
US	6097297	AU	43242/99
		WO	9962041
GB	1192421		
US	4191950		
US	4977906		
US	5291181	US	5459452
GB	2272093	DE	4336728
US	6480731	US	6129666
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			
END OF ANNEX			

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property
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International Bureau



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17 November 2005 (17.11.2005)

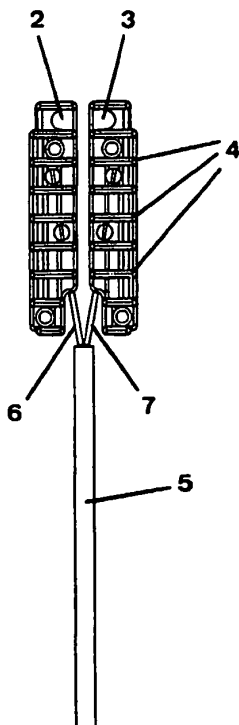
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- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: DEVICE AND APPARATUS FOR DETECTING MOISTURE



(57) Abstract: A device for detecting the presence of bodily fluid, the device including a detector (1) means having two spaced apart electrodes (2, 3), each electrode is connected to a signal generating means via a lead (6, 7). The electrodes are encased in a flexible non-conductive material with each including at least one protruding conductive element (4). The protruding elements are separated by the same distance as the spacing between the two electrodes. The device also includes a signal processing means that detects a change of state across the electrodes produced by the introduction of a fluid and an alarm actuated by the change of state.

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Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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DEVICE AND APPARATUS FOR DETECTING MOISTURE

TECHNICAL FIELD

- 5 This invention relates to a device and apparatus for detecting and monitoring bodily fluids. More particularly, but not exclusively, the invention relates to a device and apparatus for detecting urine and/or blood and/or excessive perspiration and generating an alert signal in response to such detection.

10 BACKGROUND ART

- The early detection of bodily fluids in some situations can be important to the well being of a person. For example, the early detection of any leakage of blood around the site of insertion of a dialysing needle during dialysis treatment, and in particular nocturnal dialysis, may be
15 useful. The detection of other bodily fluids such as perspiration, particularly high levels of perspiration indicating hypoglycaemia in insulin-dependent diabetics, may be important for the wellbeing and care of that person.

- Sufferers of enuresis, particularly in relation to nocturnal enuresis causing bedwetting, or
20 diurnal wetting, can be assisted by the use of a detector and alarm unit that serves to wake the person when the presence of urine is detected. A number of disadvantages with many types of devices is that they can be too small to detect the presence of bodily fluid or they can be too large and cause discomfort for the wearer. Many are made from metal, printed circuit board material or other solid and rigid materials that can cause discomfort to the extent of
25 causing significant irritation if they are in contact with the skin of the wearer. Further, some of these detecting devices are typically not durable or robust and need to be replaced after a short period of use.

- It is a non-limiting object of the invention to provide a device for detecting bodily fluid which
30 overcomes at least some of the abovementioned problems, or at least to provide the public with a useful choice.

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It is a further non-limiting object of the invention to provide an apparatus for detecting bodily fluid and generating an alarm signal which overcomes at least some of the abovementioned problems, or at least to provide the public with a useful choice.

5

SUMMARY OF THE INVENTION

According to a first aspect of the invention there is provided a device for detecting the presence of bodily fluid, the device including a detector means including at least two spaced
10 apart electrodes defining an open electrical bridge and each electrode being electrically connectable to a signal generating means via a wire, the electrodes being configured and arranged, in use, to provide a path for electricity to conduct across a predetermined distance or gap between the electrodes when a sufficient amount of bodily fluid bridges the distance or gap between the electrodes, and wherein the conductive electrodes are substantially encased
15 in a flexible non-conductive material with each conductive electrode including at least one protruding conductive element separated by the predetermined distance or gap between the electrodes.

Preferably the conductive electrodes are overmoulded with a suitable flexible non-conductive
20 thermoplastics material. Desirably the thermoplastics material is a flexible thermoplastic silicone vulcanizate material. Advantageously each said conductive electrode includes nine protruding conductive elements separated by the predetermined distance or gap between the electrodes.

25 Preferably the pair of conductive electrodes are configured and arranged with nine protruding conductive elements formed in each said electrode, the conductive elements being exposed through the overmoulded non-conductive thermoplastics material, and wherein the nine opposing conductive elements are aligned along the length of the detector means with the predetermined distance or gap between each opposing pair of conductive elements.

30

Preferably the wire is adapted to be releasably connectable to the signal processing means.

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According to a second aspect of the invention there is provided a moisture detection apparatus including the device of claim 1, and including a signal processing means configured and arranged to detect a change of state across the electrodes and actuate an alarm
5 means, and a power source means for powering the signal processing means and the alarm means.

Preferably the signal processing means and the alarm means are configured and arranged within a housing, and wherein the detector means is located remotely from the housing and
10 connected via the wire to a removably attachable connector means to the input of the signal processing means.

Desirably the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to generate a suitable input signal to an audible alarm means
15 so as to actuate an audible alarm in response to the detection of bodily fluid by the detector means.

Preferably the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to prevent current from flowing through the detecting device
20 once the alarm means is activated. Desirably the alarm is a piezoelectric ceramic speaker.

Alternatively the signal processing means includes a transmitter means that receives a suitable input signal and transmits an output signal to a receiver means, and wherein the receiver means receiving a signal from the transmitter means to actuate an audible alarm
25 means in response to the detection of bodily fluid by the detector means.

Preferably the power source means is a battery supplying a nominal six volt direct current supply.

30 Optionally the bodily fluid being detected is urine and/or blood and/or excessive perspiration.

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BRIEF DESCRIPTION OF THE DRAWINGS

5 Preferred embodiments of the invention will now be illustrated, by way of example only, with reference to the accompanying drawings in which:

- 10
- Figure 1:** Shows a side view of the electrodes and cable connected thereto before an overmoulding process;
- Figure 2:** Shows a perspective view of figure 1;
- 15 **Figure 3:** Shows a side view of the overmoulded electrodes and cable of a device 1 in accordance with one preferred embodiment of the invention;
- Figure 4:** Shows an end view of figure 3;
- 20 **Figure 5:** Shows a perspective view of figure 3;
- Figure 6:** Shows a schematic block diagram of main components of a moisture detecting apparatus 10 according to one preferred embodiment of the invention;
- 25 **Figure 7:** Shows a circuit diagram of the moisture detecting apparatus 10; and
- Figure 8:** Shows a schematic block diagram of main components of a moisture detecting apparatus 20 according to a second preferred embodiment of the invention.
- 30

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DETAILED DESCRIPTION OF THE DRAWINGS

Referring to figures 1 to 5, a moisture detection device, generally referred to as 1, according to one preferred embodiment of the invention, is illustrated.

5

The moisture detection device 1 of the invention has been designed to provide increased comfort to users by being substantially flexible and by having properties making it relatively durable and resilient.

10 In this description references are made to the detection of bodily fluid and/or moisture, and in the case of a bodily fluid it can include urine, blood and/or perspiration/sweat depending on the application of the invention. For ease of reference to these terms the following description will mainly refer to moisture, although it will be appreciated that the device 1 of the invention can detect a variety of bodily fluids.

15

The device 1 for detecting the presence of moisture includes a detecting means including at least two electrically conductive moulded electrodes 2, 3 in a spaced apart arrangement. The spaced apart arrangement is to define an open circuit bridge. The electrodes 2,3 are made of any suitable durable and resilient and conductive material, and are preferably made of a
20 conductive polymer. More preferably the electrodes 2,3 are formed of a un-plastisized conductive polyvinyl chloride ("PVC"), and including a filler of carbon black particles providing the conductive properties of the electrodes 2,3.

The electrodes preferably include raised or protruding conductive elements 4 aligned along
25 each electrode 2,3. As seen in figures 1 to 5, there are nine spaced apart protruding conductive elements 4 moulded along the length of each electrode 2,3. The electrodes 2,3 are advantageously aligned such that there are seen to be nine pairs of opposing conductive elements 4 with a predetermined distance or gap X between respective elements 4 in each electrode 2,3. The gap X can be any suitable distance and is substantially between about 2 to
30 5 millimetres in this embodiment. An advantage with this arrangement is that, when in use, moisture can be detected between any opposing pair of elements 4 and therefore the detector

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means can be considered to offer a detection device 1 that is relatively sensitive in detecting the presence of moisture.

The electrodes 2,3 are adapted to allow wires 6,7 of an electrical cable 5 to be fastened or
5 connected to respective electrodes 2,3. As seen in figures 3 and 4, the electrodes 2, 3 are advantageously encased in a suitable durable and resilient and flexible non-conductive material 8, and in this embodiment of the invention they are preferably encased in a flexible non-conductive thermoplastics material 8. More desirably, the electrodes 2,3 are overmoulded in a non-conductive alloy type thermoplastic elastomer based on vulcanized
10 silicone rubber particles in a thermoplastic matrix. One such example that can be applied to the device 1 is a thermoplastic silicone vulcanizate with a hardness of substantially about 50 shore A offering good tensile property retention and durability and hydrolytic resistance making such material particularly suitable in the device 1.

15 As seen in figures 3 to 5, the non conductive overmoulded material 8 is advantageously shaped as an elongate paddle over the elongate electrodes 2,3 and forms a flexible and durable neck 9 at the base of the paddle. The neck 9 also moulds to the outer sheath of the cable 5.

20 The cable 5 in this non limiting embodiment is a two wire 6,7 stranded cable of 0.75mm² with a PVC jacket. The length of the cable 5 in one non-limiting application is any suitable and desirable length required between the detector and the alarm means, and can be about 80cm to a metre for many applications. The other end of the cable is terminated or connected to a plug adapted to insert into a suitable socket in the input to the signal processing means as
25 detailed below.

As seen more clearly with reference to figure 4 showing an end view of the device 1, the end portions of the conductive elements 4, seen as conductive strips, protrude through the top surface of the overmoulded material 8. These protruding elements 4 are effectively the
30 contact terminals of the electrical bridge between electrodes 2,3. The device 1 has been designed to offer substantial flexibility as the device 1 can be twisted and manipulated into

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position and can be flexed during operation without splitting or breaking the device 1. Further, as the overmoulding substantially encases the electrodes 2,3 and exposed wires 6,7 making it substantially water impervious, the device 1 can be repeatedly washed, even in hot water, and reused which is desirable for hygienic given its use in blood or urine drenched applications.

The paddle device 1 is seen to be relatively thin and flexible, and is about 40 millimetres long and 20 millimetres wide, and about 3.5 millimetres in thickness. The overall dimensions of the device 1 are to allow it to function well enough to detect moisture, and be small enough to be comfortable for use by a person. However, one of the main benefits of a soft and flexible paddle shaped detection device 1 is that it can be easily inserted into place and can provide a level of comfort for users.

Referring now to figures 6 and 7, schematic and circuit diagrams of a moisture detecting apparatus, generally referred to as 10, according to one preferred embodiment of the invention, is illustrated.

The moisture detection apparatus 10 of the invention, in one non-limiting application, is designed to assist an enuresis sufferer to develop an increased sensitivity to subliminal bladder contractions and ultimately may allow a user to learn to inhibit the reflex to pass urine, particularly when asleep.

The apparatus 10 preferably includes the moisture detection device 1 as described with reference to figures 1 to 5. The cable 5 extending at one end of the device 1 is of any suitable and desirable length and can desirably include a plug connector 11 terminated at the other end of the cable 5. The plug 11 may be a mono plug, and the signal processing means 13 is adapted with a suitable connector or socket 12 for releasably receiving the plug 11 for operational purposes and for resetting the apparatus 10.

The apparatus 10 is broadly divided into main components as shown in figure 6. The sensing device 1 is electrically connected via the plug 11 to the socket 12 in a printed circuit board of

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the signal processing means 13. A power source means 14 preferably in the form of a battery comprising four button sized 1.5 volt cells supply about 6 volts direct current to the apparatus 10. The signal processing means 13 is configured and arranged with a plurality of suitable electrical circuit elements to monitor the output and state of the moisture detecting device 1
5 and to generate and process a signal suitable for feeding to the alarm indicator means 15. The alarm indicator means 15 may include any form of alert means including but not limited to an audible alarm and/or a visual display means such as, for example, a flashing light emitting diode or array of diodes (not shown) or other such indicator means to alert either a person using the apparatus 10 or a nurse or doctor or otherwise monitoring the person or patient.

10

The electrical circuit broadly represented as the signal processing means 13, the power source means 14 and the alarm indicator means 15 are desirably arranged in a compact and durable and resilient housing or casing 16. It is envisaged that the casing 16 will be as thin, lightweight and compact as possible to allow the circuitry to be protected and function
15 effectively and also provide a level of comfort for users. The casing 16 can advantageously be of a size approximating about 50 millimetres in length and about 40 millimetres in width and about 15 millimetres in thickness.

In this embodiment an audible alarm means is used as the alert indicator means 15 and
20 further details of the operation of the apparatus 10 is explained with reference to the circuit diagram illustrated in figure 7. It will be appreciated that this electrical circuit is supplied as one non-limiting example of the operation of the invention.

Referring now also to figure 7, the operation of the apparatus 10 is broadly noted as follows.
25 To power up the apparatus 10, the plug 11 of the cable 5 is inserted into the socket 12 that is mounted to the PCB and electrically connected to the signal processing means 13. This action connects a 6 volt DC power from the power source means in the form of a battery circuit 14 to the signal processing means 13. The battery circuit 14 desirably includes a filter circuit with a capacitor C3 and a resistor R6 ensuring a smoother power supply to the main
30 circuitry.

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The device 1 is generally connected in an open circuit state such that it is dry across the outer surface 8 of the paddle with a high resistance between the conductive elements 4. The capacitor C2 ensures that the main circuit powers up in the correct state when power is supplied. The capacitor C2 will initially discharge to ensure that input PIN 12 of NAND gate U1C is at logic 0 which results in the output PIN 11 of gate U1C to be logic 1, and in turn the input to NAND gate U1D to be logic 0. Positive feedback through resistor R3 further keeps the circuit in this state. Capacitor C2 will be charged through resistor R5 such that PIN 12 of gate U1C will be at logic 1.

10 The device 1 is connected through the cable 5 to the resistor R3 to form a potential divider, and a variable voltage depending on the relative resistance at PIN 13 of gate U1C. When the conductive elements 4 are bridged by moisture, the resistance drops across the elements 4 and electrodes 2,3 such that the voltage will rise across PIN 13 of gate U1C and cross the threshold of gate U1C. At this instant, both inputs to gate U1C with PIN 12 and PIN 13 will
15 be at logic 1 and the output of gate U1C will change to logic 0 resulting in both inputs to gate U1D being at logic 0 resulting in the output of gate U1D changing to logic 1 and positive feedback through resistor R3 will ensure this state remains the same until reset.

The present invention offers the additional feature of effectively isolating the electrodes 2, 3
20 of the device 1 once moisture has been detected and the main circuit has been triggered. This is achieved in this circuit by the fact that once the output of gate U1D changes to logic 1 and positive feedback through resistor R3 ensure this state remains the same, the voltage drop across the electrodes 2, 3 is reduced to 0 volts. Because the voltage across the electrodes 2, 3 and the resistor R3 are at the same voltage, there can not be any current flow across the
25 electrodes 2, 3 and therefore effectively the device 1 is isolated. This effect is desirable in applications whereby the device 1 is being used to detect urine as electrical current can cause urine to become acidic through electrolysis, with a risk of skin irritation.

As the output of gate U1D has changed to logic 1, the alarm means in the form of a piezo-
30 electric ceramic speaker BZ1 is actuated and starts beeping to alert a user to the presence of moisture. It is seen that integrated circuit U1B generates a high frequency tone at about 3.7

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kHz that is modulated on/off by operation of modulator U1A and diode D3 at a rate of about 4Hz. The modulation frequency is set by operation of capacitor C1 and resistor R2. The frequency of the speaker BZ1 is set by operation of capacitor C4 and resistors R8 and R9 and whereby the frequency and hence the volume of the speaker BZ1 can be tuned by adjusting
 5 R8 for the desired output.

Optionally if a continuous tone is required rather than an intermittent or beeping tone the on/off modulation effect can be disabled by bridging or connecting across pins TP5 and TP6 to short out capacitor C1.

10

It is seen that the output of the signal processing means 13 is buffered by the alarm indicator means 15 by operation of transistors Q1 and Q2 before driving the speaker BZ1. A bridge circuit is formed by operation of the circuit elements Q1, Q2, R11 and R13 resulting in a drive signal fed to the speaker BZ1 that is almost double the supply voltage of 6 volts.

15

It is seen that the speaker BZ1 will continue to emit a tone until the cable 5 is unplugged from the socket 12 which causes the circuit to be turned off.

The apparatus 10 is considered to be particularly suitable for use by enuresis sufferers. As
 20 the casing 16 is quite compact, it can adapted to be attached to a user's clothing by any suitable fastening means. In the case of problems with enuresis sufferers who are sleeping, suitable attachment means for attaching the casing 16 housing the main circuitry can be provided so that the casing unit 16 is attached close to the head of the wearer.

25 In one application of the apparatus 10 for an enuresis sufferer, the casing 16 part of the apparatus 10 can be attached to the shoulder or associated clothing of a wearer such that the alarm indicator means 15 is mounted close to the wearer's head. The cable 5 can be plugged into the socket 12 and the device 1 can then be positioned inside his or her pants in a suitable position to detect the presence of urine when the user passes urine. It is seen then that when
 30 urine closes the electrical bridge between at least any one respective pair of elements 4 between electrodes 2,3 the alarm indicator means 15 will be is activated and the sleeping

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person should wake up and be made conscious of the fact that they are passing urine. It is seen then that the alarm advantageously functions as a stimulus to assist in bladder training by the person wearing the apparatus 10 of the invention. Once activated the user may remove the plug 11 from the socket 12 and later reinsert the plug 11 to reset the apparatus 10.

5

It is further considered that the apparatus 10 of the invention may also be useful for applications such as the detection of blood leaking around the site of insertion of a needle during dialysis, particularly during nocturnal dialysis. Further, high levels of perspiration may be detected for persons suffering hypoglycaemia in insulin dependent diabetics.

10

Referring now to figure 8, a schematic block diagram of main components of a moisture detecting apparatus 20, according to a second preferred embodiment of the invention, is illustrated. In this embodiment the device 1 is close to the signal processing means and the alarm means can be placed remote from the device 1 by a user or by another person

15 reasonably close that is monitoring the person wearing the sensing device 1.

In this apparatus 20, the cable 5 from the moisture sensing device 1 is connected to terminals of a signal processing means 21. The signal processing means 21 also includes a transmitter 22. The transmitter 22, once activated when the signal processing means detects and
20 processes a positive signal from the device 1, transmits a suitable signal to a receiver means 23 that is fed to a control means 24 that is adapted to trigger an alarm indicator means 25. Many aspects and principles of this electrical circuit and associated elements can be similar to the apparatus 10 as already described and will not be repeated.

25 One method of operation is broadly described as follows. The signal processing means 21 is configured and arranged to monitor the resistance across the electrodes 2, 3 of the device 1. A suitable power supply means in the form of a battery is provided along with a suitable on/off switch. When the resistance drops below a predetermined threshold level because urine has formed a conductive path across elements 4 between electrodes 2,3, the output of an
30 integrated circuit formed as a schmitt trigger changes state such that its output changes to logic 0 and this change of state is sensed by an input to a second integrated circuit (IC), such

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as, for example, an Atmel AT86RF401 IC functioning as a signal processor and radio frequency microtransmitter operating in a band of between about 300 to 450 MHz. When the second IC receives a signal indicating that moisture on the device 1 is present, it starts transmitting at about 750 bps at a low power level of about 1 milliwatt at a frequency of say
 5 about 315.788 MHz. The antenna that is used may be a loop antenna that set in place around the outside of a printed circuit board to which components of the signal processing means 21 and related elements are mounted.

The transmitting signal may be encoded if required, and data that is transmitted may be a 32
 10 bit number unique to the transmitter. The transmitter repeatedly transmits the data to be received by an associated receiver means 23 that is monitoring for transmission of the unique 32 bit number.

The receiver means 23 is also desirably battery powered and includes a suitable radio
 15 frequency receiver (for example a Micrel MICRF009BM IC) and associated circuit elements and RF antenna, signal processing means including a microprocessor controller unit (for example an ATMEL ATTINY12 IC) referred to as a control unit 24, with associated circuit elements, and a suitable alarm indicator means 25.

20 The receiver circuitry can be configured to constantly monitor for the particular 32 bit data that may be transmitted from the transmitter means 22. If the transmitter means 22 is transmitting the 32 bit data once activated by the device 1, the receiver means 23 will receive the signal and feed the signal to the microprocessor control unit 24. The control unit 24 then pulses an oscillator circuit that drives the alarm indicator means 25 in the form of a buzzer or
 25 piezo-electric speaker.

The circuitry at the transmitting side is housed in a suitable compact casing 26. The circuitry at the receiving side is also housed in a suitable compact casing 27.

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It is considered that the alarm means 25 can be conveniently positioned anywhere within the signal receiving range of transmission, and as such can be either close to the user or be remotely monitored by a caregiver or nurse or other person monitoring the user.

- 5 Wherein the foregoing reference has been made to integers or components having known equivalents, then such equivalents are herein incorporated as if individually set forth. Accordingly, it will be appreciated that changes may be made to the above described embodiments of the invention without departing from the principles taught herein.
- 10 It is to be understood that the above description is intended to be illustrative, and not restrictive. Additional advantages of the present invention will become apparent for those skilled in the art after considering the principles in particular form as discussed and illustrated. Thus, it will be understood that the invention is not limited to the particular embodiments described or illustrated, but is intended to cover all alterations or modifications
- 15 which are within the scope of the appended claims.

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CLAIMS:

1. A device for detecting the presence of bodily fluid, the device including a detector means including at least two spaced apart electrodes defining an open electrical
5 bridge and each electrode being electrically connectable to a signal generating means via a wire, the electrodes being configured and arranged, in use, to provide a path for electricity to conduct across a predetermined distance or gap between the electrodes when a sufficient amount of bodily fluid bridges the distance or gap between the electrodes, and wherein the conductive electrodes are substantially encased in a
10 flexible non-conductive material with each conductive electrode including at least one protruding conductive element separated by the predetermined distance or gap between the electrodes.
2. A device according to claim 1 wherein the conductive electrodes are overmoulded
15 with a suitable flexible non-conductive thermoplastics material.
3. A device according to claim 1 wherein the thermoplastics material is a flexible thermoplastic silicone vulcanizate material.
- 20 4. A device according to claim 3 wherein each said conductive electrode includes nine protruding conductive elements separated by the predetermined distance or gap between the electrodes.
5. A device according to claim 3 wherein a pair of conductive electrodes are configured
25 and arranged with nine protruding conductive elements formed in each said electrode, the conductive elements being exposed through the overmoulded non-conductive thermoplastics material, and wherein the nine opposing conductive elements are aligned along the length of the detector means with the predetermined distance or gap between each opposing pair of conductive elements.
- 30

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6. A device according to claim 1 wherein the wire is adapted to be releasably connectable to the signal processing means.
7. A moisture detection apparatus including the device of claim 1, and including a signal processing means configured and arranged to detect a change of state across the electrodes and actuate an alarm means, and a power source means for powering the signal processing means and the alarm means.
8. An apparatus according to claim 7 wherein the signal processing means and the alarm means are configured and arranged within a housing, and wherein the detector means is located remotely from the housing and connected via the wire to a removably attachable connector means to the input of the signal processing means.
9. An apparatus according to claim 7 wherein the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to generate a suitable input signal to an audible alarm means so as to actuate an audible alarm in response to the detection of bodily fluid by the detector means.
10. An apparatus according to claim 7 wherein the signal processing means includes an arrangement of circuit elements configured and arranged, in use, to prevent current from flowing through the detecting device once the alarm means is activated.
11. A device according to claim 9 wherein the alarm is a piezoelectric ceramic speaker.
12. An apparatus according to claim 7 wherein the signal processing means includes a transmitter means that receives a suitable input signal and transmits an output signal to a receiver means, and wherein the receiver means receiving a signal from the transmitter means to actuate an audible alarm means in response to the detection of bodily fluid by the detector means.

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13. An apparatus according to claim 7 wherein the power source means is a battery supplying a nominal six volt direct current supply.
14. A device according to claim 1 wherein the bodily fluid being detected is urine and/or blood and/or excessive perspiration.
15. A device substantially as herein described with reference to any one of the accompanying drawings.
- 10 16. An apparatus substantially as herein described with reference to any one of the accompanying drawings.

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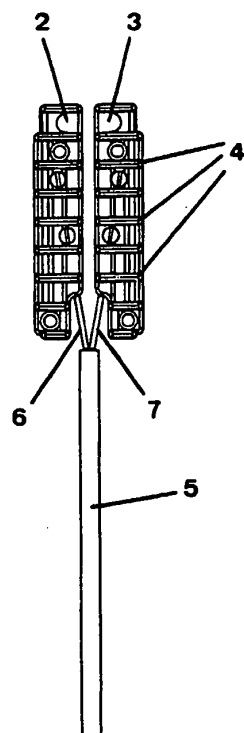


Figure 1

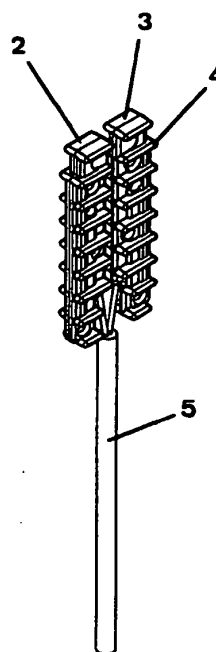


Figure 2

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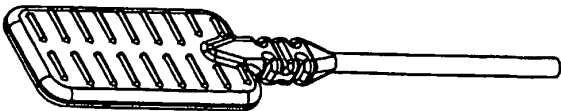


Figure 5

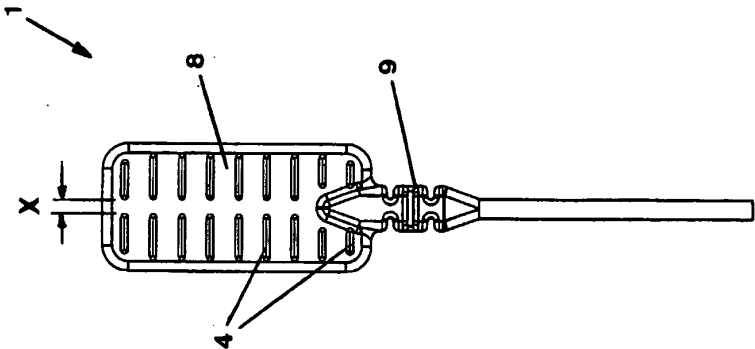


Figure 3

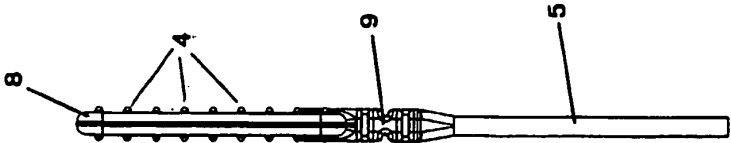


Figure 4

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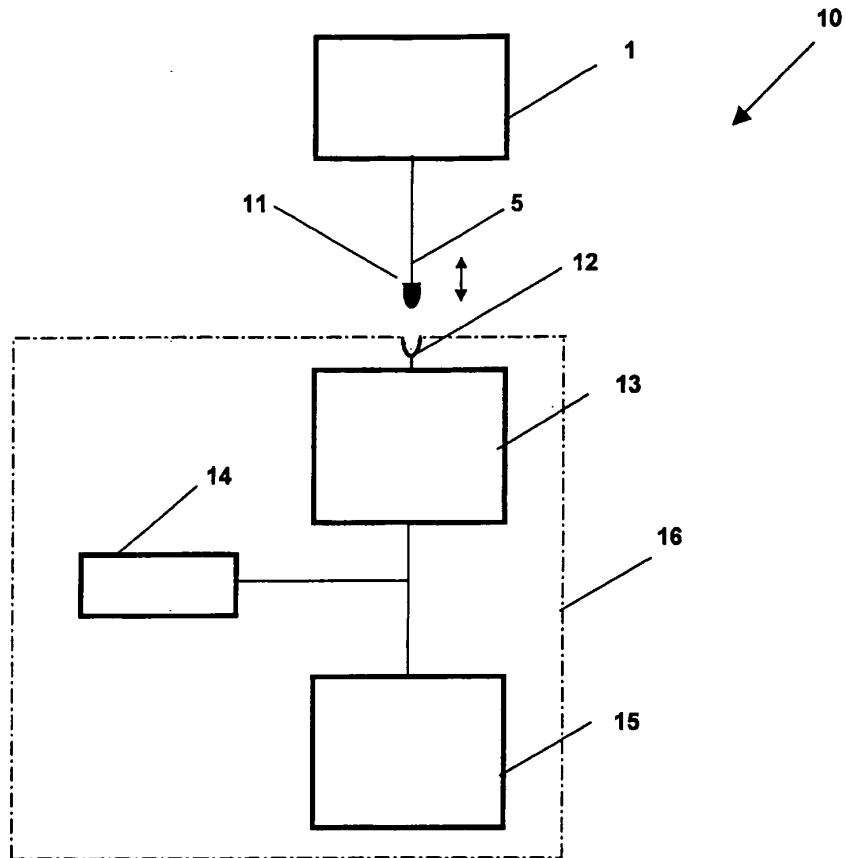


Figure 6

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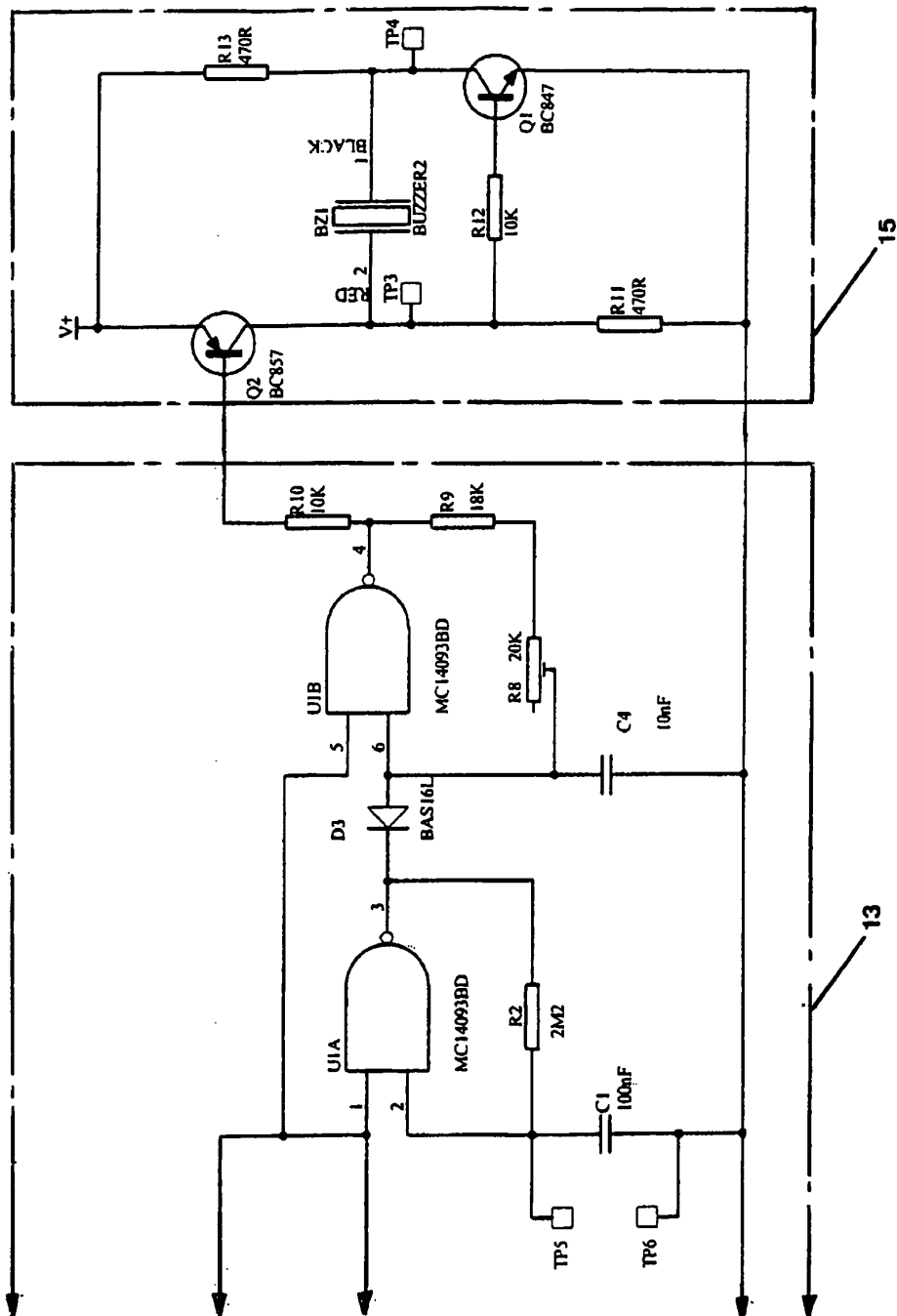


Figure 7

(arrows and circuit diagram continued on sheet 5/6)

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(arrows and circuit diagram follow from sheet 4/6)

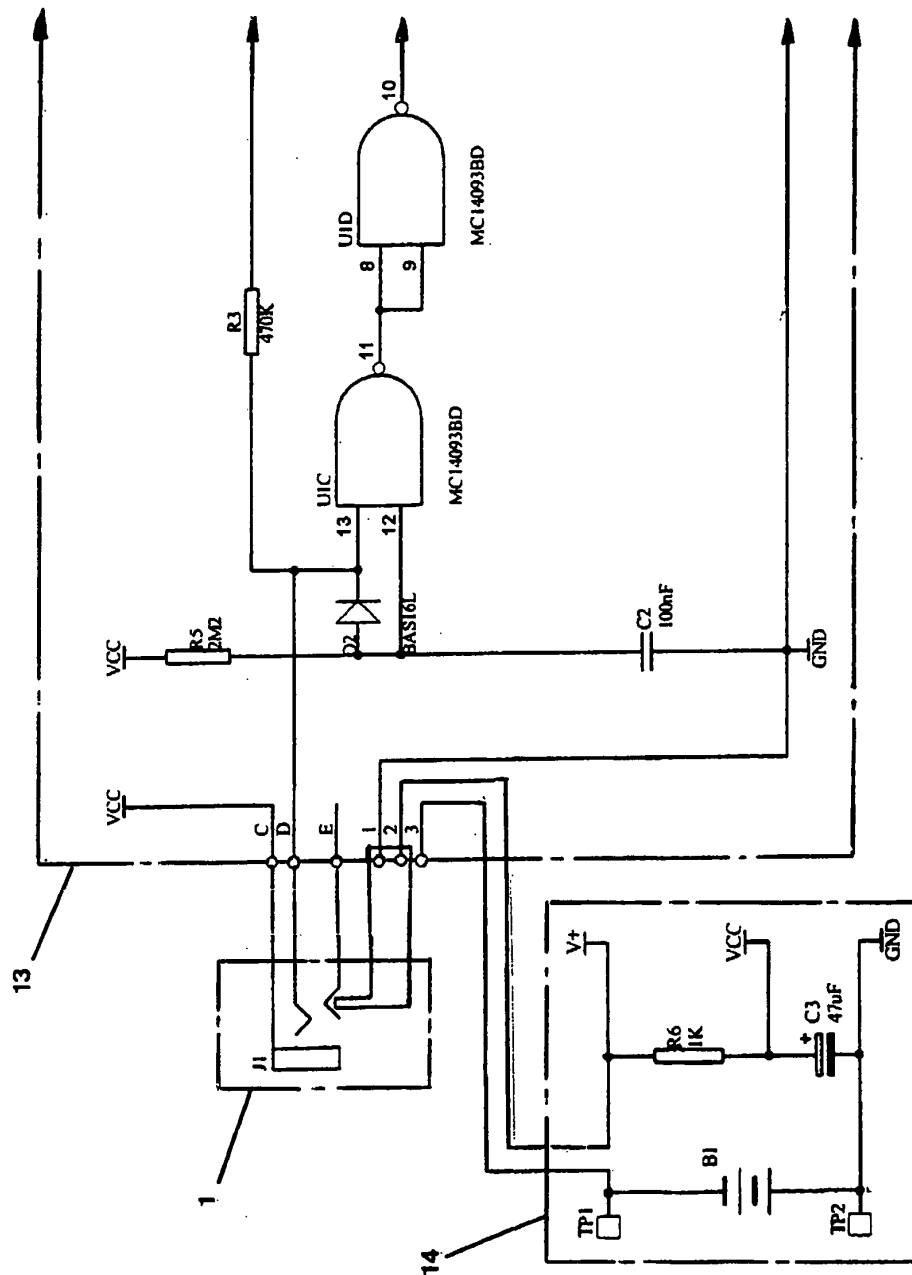


Figure 7

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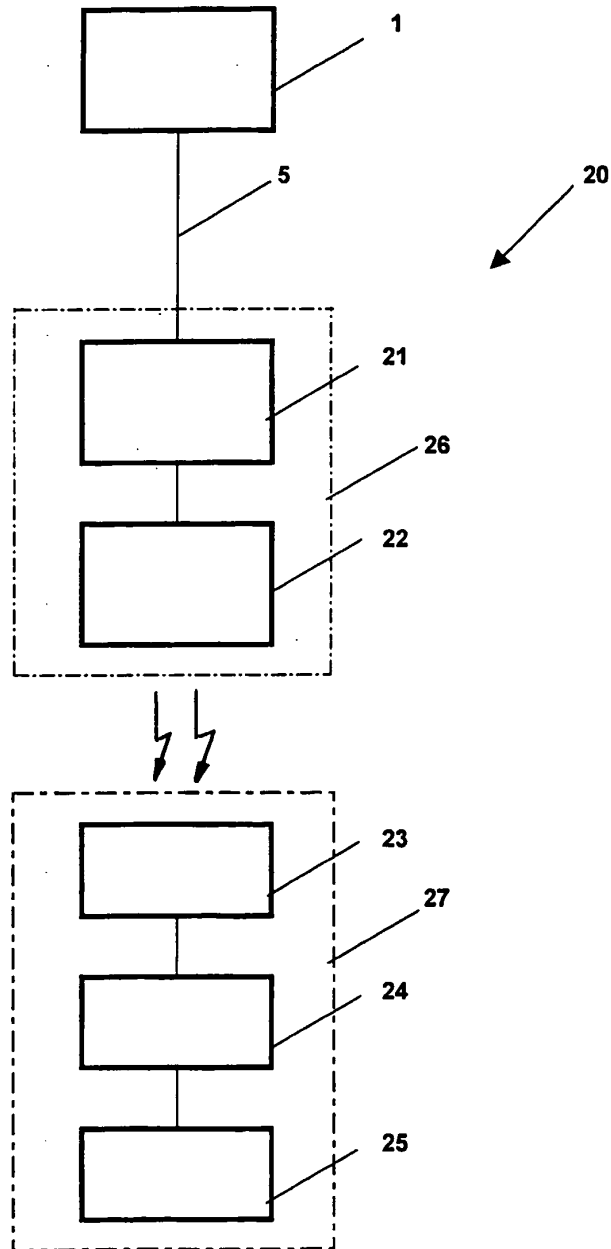


Figure 8

SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/NZ2005/000100

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. ⁷: A61B 5/00 G08B 21/20 A61F 5/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

ECLA: A61B 5/00E G08B 21/20, 21/20 A61F 5/48 AND KEYWORDS

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI: A61F A61B G08B G01N G01R fluid water blood exudate urine excret faece moist sweat perspiration wet damp electrode lead terminal contact conduct electric detect sense monitor determine indicate measure discover note observe diabet enuresis bed hypogl alarm sound siren audio audit buzz warn alert protrusion projection lump lump lug bump ridge raise space gap separate encase seal enclose

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 1981000045 A1 (DIA-MED, INC.) 22 January 1981 Page 3 line 35 to page 4 line 18, figures	1-3,7,9,11,13-16
Y		8, 12
Y	US 4374379 A (DENNISON) 15 February 1983 Entire document	1-3,6-16
X	DE 3823859 A1 (KELLERBERG) 18 January 1990 Column 2 line 60 to column 4 line 4, figures	1-3,7,9,11,13-16
Y		8, 12
X	WO 1999063497 A1.(KIMSEY) 9 December 1999 Entire document	1-3,6-16

☒ Further documents are listed in the continuation of Box C☒ See patent family annex

* Special categories of cited documents:

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"P" document published prior to the international filing date but later than the priority date claimed

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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"&" document member of the same patent family

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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y Y	US 5557263 A (FISHER et al) 17 September 1996 Entire document	8, 12 1-3, 6-16
Y Y	US 6097297 A (FARD) 1 August 2000 Column 7 line 61 to column 8 line 49, figure 1	8, 12 1-3, 6-16
A	GB 1192421 A (COHEN) 20 May 1970 Entire document	
A	US 4191950 A (LEVIN et al) 4 March 1980 Column 4 lines 37 to 56	
A	US 4977906 A (DI SCIPIO) 18 December 1990 Figure 2, column 5	
A	US 5291181 A (DEPONTE) 1 March 1994 Figures	
A	GB 2272093 A (SMITHS INDUSTRIES PLC) 4 May 1994 Entire document	
A	US 6480731 B1 (DELUCA et al) 12 November 2002 Figures 16 and 17	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/NZ2005/000100

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member	
WO 8100045	EP 0031841	US 4365637	
US 4374379			
DE 3823859			
WO 9963497	AU 42742/99	EP 1082711	US 6373395
US 5557263	AU 47882/93	EP 0663097	EP 1063624
	US 5790036	WO 9402918	
US 6097297	AU 43242/99	WO 9962041	
GB 1192421			
US 4191950			
US 4977906			
US 5291181	US 5459452		
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US 6480731	US 6129666		
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.			
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PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM,
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— without international search report and to be republished
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For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: PATIENT MONITORING SYSTEM

(57) Abstract: A patient monitoring system according to one embodiment includes a real-time wetness sensor configured to detect the rate of change in wetness occurring within an associated diaper, and automatically adjusting the sensitivity of the sensor to account for a wetness event unrelated to urination. A monitoring unit may be utilized in such a manner that the monitoring system controller monitors the wetness sensor and generates data associated with detected wetness events relative to the diaper. A wireless transmitter configured with the monitoring unit and in communication with the monitoring system controller may be further utilized to send the generated data, through a host computer, to a caregiver unit having a caregiver system controller in communication with the host computer. The caregiver can then check the status of the patient, provide a service, and annotate the patients history by transmitting the recorded observation and service provided back to the base station.

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Patient Monitoring System

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Background of the Invention

1. Field of the Invention

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The present invention relates generally to a patient monitoring system, and in particular, to a patient monitoring system that permits accurately detailed wetness sensing and integrated caregiver management.

2. Description of the Related Art

There are numerous devices and systems targeted to the problem of detecting and reporting wetness in a diaper or similar article. None of these systems have earned wide commercial success. Accuracy is both a persistent problem for these market participants and a heretofore unrecognized opportunity for a product that is able to detect for wetness in a diaper in a way that accounts for a variety of problems.

A number of devices and wetness detecting systems have been attempted to report when a diaper, bedding, or adult incontinence article becomes wet due to incontinence. These devices frequently report erroneous detection wet incontinent related conditions due to a variety of problems, such as: perspiration generated by the wearer of the article; fluctuations in electrostatic capacity caused, for example, by movement of the wearer of the diaper, and even climatic differences that may cause excess humidity in the diaper or similar article.

Patients and other users of diapers with bladder incontinence often share other infirmities that require the frequent attention of a caregiver. Devices that provide false wetness indications may result in a lower quality of care for the patient if the caregiver

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becomes conditioned to frequent erroneous reports of wetness and therefore neglects to provide a reasonable standard of care.

Some have approached this problem with attempts at permitting a nominal level of integrated caregiver management facility to this problem. These systems often focus on the passive participation of the caregiver and neglect the opportunity to fully engage the caregiver as an active participant in addressing the direct and related needs of incontinent patients, thereby missing the chance to raise the quality of care for the patient.

Brief Summary of the Invention

The primary object of the invention is to provide a diaper with an improved wetness detector.

Another object of the present invention is to provide an improved wetness detector that can monitor the rate of change of the level of wetness in an article.

A further object of the present invention is to provide real-time wetness sensing that can automatically adjust sensitivity to account for otherwise false or erroneous wetness events such as static electricity, movement, humidity, and the like.

A still further object of the present invention is to detect other patient infirmities or problems related to their incontinent condition.

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Yet another object is to provide a patient monitoring system where the quality of care and degree of accountability of caregivers is improved, by integrating them into the monitoring-information system through their recording of observations and services provided to patients.

Other objects and advantages of the present invention will become apparent from the following descriptions, taken in connection with the accompanying drawings, wherein, by way of illustration and example, an embodiment of the present invention is disclosed.

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Brief Description of the Drawings

The drawings constitute a part of this specification and include exemplary embodiments to the invention, which may be embodied in various forms. It is to be understood that in some instances various aspects of the invention may be shown exaggerated or enlarged to facilitate an understanding of the invention.

This invention will be better understood by referring to the accompanying drawings, wherein:

FIG. 1 is a block diagram showing one embodiment of the present invention;

FIG. 2 is a detailed view of a preferred sensor implementation according to one embodiment of the present invention;

FIG. 3 is a diagram of a caregiver unit having several user interface features in accordance with some embodiments of the present invention;

FIG. 4 representatively shows a schematic circuit diagram of a resistor divider network that can be employed with the present invention;

FIG. 5 representatively shows a schematic circuit diagram of a low battery detector that can be employed with the present invention;

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FIG. 6 representatively shows a schematic circuit diagram of sensor detectors that can be employed with the present invention;

FIG. 7 shows a circuit schematic of a caregiver unit suitable for use in the present invention;

FIG. 8 representatively shows a schematic circuit diagram of sensor detectors that can be employed with the present invention;

FIG. 9 representatively shows a schematic circuit diagram of a dynamic resistance selecting comparator based sensing technology circuit that can be employed with the present invention;

FIG. 10 is a diagram of a state machine algorithm of dynamic resistance selection in accordance with some embodiments of the invention;

FIG. 11 representatively shows a schematic circuit diagram of a real-time, adaptive wet sensing circuit that can be employed with the present invention;

FIG. 12 representatively shows a schematic circuit diagram of a micro controller-based real-time, rate of change wet sensing circuit that can be employed with the present invention;

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FIG. 13 shows a circuit schematic of a mommy unit suitable for use in the present invention.

FIG. 14 shows a circuit schematic of a patient unit suitable for use in the present invention.

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Detailed Description of the Preferred Embodiments

Detailed descriptions of the preferred embodiment are provided herein. It is to be understood, however, that the present invention may be embodied in various forms. Therefore, specific details disclosed herein are not to be interpreted as limiting, but rather as a basis for the claims and as a representative basis for teaching one skilled in the art to employ the present invention in virtually any appropriately detailed system, structure or manner.

As used herein, the term "diaper" refers to garments or pads which are placed against or in proximity to the body of the wearer to absorb and contain the various fluids discharged from the body. A non-exhaustive list of examples of absorbent articles includes diapers, diaper covers, disposable diapers, training pants, pants-type diapers, feminine hygiene products, and adult incontinence products.

The terms "base station", "display unit", "host", and "host computer" as used herein interchangeably, and all refer to a computer or computing device for displaying, recording, and/or managing data.

The terms "wetness" and "wetness event" are to be understood as including human urination, defecation, and other bodily discharge events.

The following descriptions are of various embodiments of the present invention.

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Infant Diaper Sensor

This system is to notify when a diaper becomes wet. The sensing materials have been refined to aluminum and polymer backing and conductive thread. The novel electronics offers the capability to sense in real-time with adjustable measurement capability. It can change the level of the comparator and account for static and other transient effects. It is these effects which have really been the cause that no system has been effective on the market to date, particularly in disposables which generate significant levels of static.

The method of connecting the sensor to the diapers is currently with snaps. However, flex connectors and Velcro sewn with the conductive thread can also be used. In this case, the electronics would just fasten over the Velcro portion of the waist of the disposable and make the connection directly to the conductive thread.

Any of the standard means of notification can be used with this system, including, alarms, bells, whistles, recorded playback, RF transmission to a remote site.

Toilet Training

The basic concept is to toilet train a child. The system will work with disposables, toilet training cotton pants, or any other clothing. The concept is to create a link for the child between wetting and the toilet. The problem with toilet training is that children are found wet after the fact and do not have sufficient cognitive abilities to connect an event that

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happened 10 minutes earlier with what the parents are saying in the present. The concept is to provide instant notification of wetting so that parents or caregivers can then take the child to the bathroom to finish going to the bathroom in the toilet, or to discuss that what just happened in their diaper needs to happen in the toilet.

Electronics and connections are the same as in the diaper notification. There is a record and playback option on this system, where a parent or caregiver can record a short message to be played upon wetting, such as „don't wet in your diaper, come find me and I will take you to the toilet.“ This makes the connection to the present event immediate and significant.

Daycare Center System

This system is developed specifically to permit the caregivers to know immediately that a child in the daycare is wet. The novel component to this system is that the software allows for the system to accommodate all the children in a daycare with only a single receiver. Each child has a coded transmitter and the system can decode that transmission to the individual child. Normally, this transfer is a 1:1 system. In this case, it is 1000:1. This is critical because of cost considerations.

Following is a brief of the RF system used, although there are other frequencies and systems that could be developed. This system uses 418 MHz and a transmit or no transmit system. This is important because FCC rules consider the total transmit time in their power calculations, and since less than half of the transmission time is off (that is,

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data is being sent while in the off state) the system can have significantly higher power and resultant range than current 802.11 or WIFI applications. One of the features of the system that is most appreciated is the fact that pictures pop-up on the screen showing the child or children who are wet. The transmitted data is encoded into the xilinx chip at the transmitter, and the bits are serially streamed to the transmitter at 1KHz rate. This rate can be adjusted and changed if needed. There is also no limit to the length of the bit stream being transmitted. Programmable features of the xilinx chip allow for significant savings in power because the chip can shutdown everything but the oscillator while waiting for a wet event. Even in the most simple existing circuits the battery life is significantly shorter because the comparator and oscillator are continuously running and don't have sleep features.

All of the advantages of using real-time as explained earlier apply to this application as well. This chip also allows smart programming such as verifying when the diaper has been changed and that a diaper is attached and not the system merely disconnected. It also automatically retransmits updates when the status of the unit changes (i.e., wet, disconnected, new dry diaper), and can be programmed to trigger at subsequent wettings without changing on the initial wetting.

Bedwetting Unit

This unit can use normal garments with the sensor sewn into a liner, or it can be disposable such as a pullup. This unit is a wireless RF unit having the same transmitter and functions as the Patient Monitoring System. It has additional electronics to make it

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re-chargeable and in fact the transmitter and sensing unit worn by the enfant would during the daytime hours, be placed into the bedside unit which would have not only the alarm and transmitter, but also a recharger stand and electronics.

The basic operation is wetness sensing, transmission to a bedside stand, which would be plugged into an electrical socket. The bedside unit has the high decibel alarm along with a reset button. The bedside unit further includes the receiving antenna and a repeater, which would re-transmit the alarm signal to a remote beside unit in the parents or caregivers room. The bedside also has additional programmable features, such as an alarm clock which can be set to awaken the bedwetter prior to the normal time which he wets each night. It is also programmable for decibel level, a voice recording that would call the bedwetter by name and not just an sound alarm, since the bedwetter usually wakes quicker when they are called by name, it could also have a light incorporated in it, and this light can be programmed as with the alarm.

The unit in the parents or caregivers room is the receiver and alarm with reset. If the child wakes up on his own and resets his bedside unit, the parents unit automatically resets, letting them know that the child is up and taking care of things. The transmitter for the child has the capability of automatically determining whether it is disconnected or attached to a dry sensor. It can also calibrate at each reset with the body mass of the wearer to hold in memory a real-time capacitance measure that ensures the diaper is being worn and not just attached to an empty diaper.

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Patient Unit

The patient unit is worn by the patient. It has wetness sensing capability in real-time. In addition, it contains a magnetic switch used to record visits to the wearer, it has motion detection capability, fall indicator, leaving a restricted area indicator, GPS locator capability, a call button and an emergency call button. Some of these actions are activated by the wearer and others are activated externally or automatically. All data is transmitted by RF to the basestation using the same serial transmission function described previously.

Caregiver Unit

The caregiver unit is a handheld application. The caregiver can select the patient ID or room number, care that has been given and observations. The care and observations can be adapted to the needs of the facility. Once selected, an LED lights up indicating that the action has been selected. Once the caregiver has selected all the appropriate services which have been rendered and observations made, a send button is pushed and the appropriate information is sent by RF to the base station. The caregiver unit is icon driven and requires no English or particular language skill. The application could just as easily be prepared on a handheld however and interfaced to the same base unit. This handheld is easily programmed to various languages or application icons changed by selection from a menu.

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The handheld also receives input from the base station indicating critical patient status, or next item in the queue on the handheld screen. The handheld also records which caregiver gave the service or observation and date and time stamps.

The base station is comprised on the receiver and software. The caregiver unit's digital output is fed serially into the computer where the software decodes the information and appends the appropriate services and observations to the patient's record.

The base station also records events which need attention to the screen or handheld of the caregivers. The screen is prioritized according to time of event and critical nature of the event. When the event has been taken care of, it is automatically removed from the queue.

The base station further logs all diaper activity. The base station provides reports on diaper use and changing statistics, displays the current diaper status of all babies and their name and picture. Users can customize the number of insults before a change is required for each baby. It further logs all diapers used and automatically fills out an order form for new diapers. Provides audio and visual notification of all new diaper activity. Automatically keeps detailed records all requests for care and services provided for each individual.

Mommy Unit

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The mommy unit is an RF unit between the infant and the mother. The infant has the normal detection unit comprised of the xilinx PLD and detectors but in addition to the output of tune, recorded message, LED, etc, it also has an RF transmitter. When the RF transmitter is selected, all the other output means are disabled. The RF is transmitted to a unit which the mother has. It can be set to beep, tune, or vibrate. Any of the standard notification modes. When the child becomes wet, the mother is immediately notified by one of the means described.. The mommy unit as with all the mobile receiver units will have a RF level detection circuit that allows the portable receiver to be powered down until the initial RF burst detected by a parallel diode scheme. The DC component generated by a RF burst through this diode combination is used to „wake up“ the receiver for the incoming transmitted serial bit stream.

The mommy unit allows for toilet training and wet diapers to be monitored in a public setting without embarrassment to child or parent and at the same time without interrupting toilet training or care to the infant.

The following detailed descriptions are of the preferred embodiments of the present invention.

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Patient Module

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The patient module is a CMOS based RF design which is used to both collect and transmit the patient information to the host. The patient module consists of a small 2x2.5 inch case which contains the electronics as well as ports which permit input from the patient. The heart of the patient module is the logic chip. The patient module uses a Xilinx PLD, Coolrunner, 128 macro cell. Each of the patient module inputs goes into the xilinx chip. The inputs for the patient module are: 1) visit; the visit is activated by a magnetic reed switch. This is to ensure that the caregiver has to be present at the patient location. If there are patient items in the queue, a visit will clear those items temporarily. If they have not corrected the item in the queue, then the item will immediately return to the queue. If no patient items are in the queue, then activation of this switch is considered as just a visit. The visit is transmitted according to the process that will be described later in the transmit section. 2) Wet; a wet signal is generated by way of a comparator op amp. When the resistance in the disposable diaper drops as a result of wetness, this resistance change is measured at the inputs of the comparator and causes the output to switch low. The threshold of the op amp is determined by a resistor divider network as shown in FIG. 4. The low output is detected by the xilinx chip where it activates a send. The patient name, is transmitted to the queue and remains there until a dry diaper is on the patient and the visit button is wanded. This then clears the queue and annotates the patient history that they have been changed and are now dry. 3) Low Battery detector. This circuit is also a comparator op amp. A trigger voltage level is placed on one side of the comparator. The other side of the op amp is tied to VCC. When the voltage level provided by the battery drops to the level of the trigger voltage, a low is presented at the output of the comparator as shown in FIG. 5. A low battery signal is detected by the xilinx and initiates a low battery message to be

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transmitted 4) Call Button. The call button is patient activated. It is used to notify the caregiver that something is required by the patient. When the patient pushes this button a high is sent to the xilinx chip and transmitted. The patient name and request for assistance is placed into the queue. When the patient is visited by the caregiver, the caregiver passes his token across the face of the patient module and the request for service is replaced by a notation in the patient queue that he was visited. It also denotes time and date of visit 5) 911 call. This button is pushed by the patient when they think that an emergency has arisen. It can be programmed or left disabled depending on the cognizance of the patient. This differs from the call button in that when this transmission is received by the management system, it appears in bold and red and in much larger print which flashes and beeps. It continues this transmission until cleared by a check from the caregiver. 6) Movement indicator. This records the number of times that a patient rocks and the intensity of the rocking. The software counts each transmission and when the number of movements in a specified time period reaches the patient programmed amount, the patient is sent to the queue. The intention of this is to monitor how agitated a patient is becoming prior to them trying to get out of their chair or stand up or falling. As with other patient module indicators, it is reset and removed from the queue by a caregiver visit, who is help the person readjust themselves, or perhaps stand for a bit or take a walk. The objective is to predict and prevent a fall. 7) Fall indicator. If a patient should happen o fall, this reed switch opens to indicate that they have fallen and need assistance. This transmission as for the 911, flashes, is in red, is larger print and beeps to assist in immediate recognition. 8) Location indicator. This inputs comes from sensory locators on the patient which when passing through monitors in a restricted area sends a high to notify that the person has

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left or entered a restricted area. As with the 911 and fall indicator, this indicator to the queue is in bolded, caps, red and flashing font with beep. The transmission sequence for the patent module is as follows: The first 4 bits are sync bits. They are hard coded and should be high, low, high, high.

The next 3 bits are ID bits. These bits are what you will use to determine who is sending the data.

001 Patient

010 Caregiver

011 Nurse

100 Physician

When you decode these bits, you will use them to determine which table you will address to decode the remainder of the data in the stream.

The next 9 bits are patient ID bits.

000000001 - will be patient 1. These bits are binary and will be tied to the patient file.

All data in the data stream will be tied to the patient file by way of this identifier.

The next 5 bits are tied to the caregiver modules. They have no application to the patient module and therefore they remain zeros.

The next 12 bits are the service bits. These bits are not binary. Each bit represents a service.

100000000000 Assisted with transfer

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010000000000	Bathed
001000000000	Cleaned Bathroom
000100000000	Bed Made
000010000000	Assisted in Dressing or Hygiene
000001000000	Footcare
000000100000	Incontinence Care
000000010000	Linens Changed
000000001000	Oral Care
000000000100	Showered
000000000010	Therapy
000000000001	Toileting

Any or all of these bits can be simultaneously transmitted and each service then has to be recorded in the file for the patient ID which accompanied the transmission.

The next 12 bits are not used and remain in the zero state.

Any or all of these bits can be simultaneously transmitted and each observation then has to be recorded in the file for the patient ID which accompanied the transmission.

The last 3 bits are end of transmission bits. We should verify, sync and end of transmission bits to be sure we have everything.

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FIG. 14 is a schematic circuit of the patient. This module is part of the assisted living / elderly patient caregiver monitoring system.

The patient module consists of several different sensors that when triggered send a message via RF back to a computer that logs the event, the patient ID and the time the event occurred. One of the sensors is a wet detection sensor. The sensor part of this module is identical to the infant sensor and will not be covered again. The interface to the comparator for the RF notification circuit is xilinx CPLD. A CPLD is a programmable logic device that can be programmed to perform a specific function. The CPLD in the RF Notification monitors all the sensor inputs, including the wet event sensor, when it detects an event it logs the event. Once the event has been logged it transmits to the base station the even that has just occurred along with an ID so the computer can attach the event to a specific person. The transmission range of this system is dependant on a number of factors; distance, line of sight, height placement of transmitter and receiver, battery level in the transmitter, transmitter/receiver frequency.

The critical component to the comparator sensor system is the selection of the reference resistors. The reference resistors determine the sensitivity of the system and ultimately the sensor ability to accurately detect a wet event. One concern with this sensing method is the ability for the sensor to discern between a wet event and wetness cause perspiration. With the correct selection of the resistors in the reference resistors network this false detection could almost be eliminated.

Testing required to determine these values is as follows:

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- 100s of resistance measurements need to be made on diapers as they are being wet.
- Resistance curves versus wetness need to be generated from test data
- Resistance measurements need to be made on diapers that our not wet but the wearer is perspiring. A perspiration simulator needs to be develop to accurately modal perspiration so higher volume tests can be conducted in the lab.
- Resistance curves versus perspiration need to be generated from test data
- With these results different resistor networks can be chosen implemented and tested to determine if they are correct.

Adaptive Wetness Sensing Technology

This new sensing circuit is an improvement over simple comparator based systems and eliminate the false alarm detection of perspiration. The difference between this wet sensing technology and the simple comparative wet sensing units is the ability for the unit to change it's dynamic range of operation by selecting different values up pull up resistance or sample the actual voltage across the diaper and record the rate of change of voltage to determine if a wet event has occurred.

Dynamic Resistance Selecting Comparator Based Sensing Technology

The ability to dynamically change the comparator pull up measurement resistance allows the sensor operate through numerous wet events and give the unit the notification section of the unit the ability to uniquely feedback to the user which wet state the sensor is currently. This directly translated to a rough saturation level in the diaper.

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The sensor currently built with this type of sensing feature is illustrated in FIG. 9. The two resistors hanging off of the minus input of the comparator and connecting into the Xilinx is what makes this unit unique. RES_1 and RES_2 outputs of the Xilinx are Tri state controlled output of the Xilinx. This gives the sensor the ability to cycle through the resistance values changing the amount of wetness it will take in the diaper for the sensor to trigger. RES_1 = 50K and RES_2 = 25K in this schematic. When the sensor is reset and placed onto the child RES_1 output is driven high and RES_2 is in a tri-state. This will give place a 50K pull up value on the input of the comparator. The diaper will have to reach a resistance of this level before it will trigger. At the time the child wets the sensor will trigger and in the case of the Wireless infant unit it will send a message to a receiver notifying it of the wet event and also that it was the first wet event of the current diaper. After the notification the sensor switches RES_1 to tri_state and RES_2 turns on. In the case of the Wireless Infant unit this will place 25K pull up on the diaper sensor input. This will require the diaper resistance to drop to 25K before it will trigger which will result in the second wetting of the diaper. Once this level is triggered the same notification mechanism is triggered but this time the unit sends to the receiver the message that RES_2 has been triggered thus this is the second wetting. After the notification period the sensor turns on both RES_1 and RES_2 placing the parallel combination of the two resistances on the input of the comparator. In the case of the Wireless infant unit this will be approximately 16K. This level will not trigger until the third wetting. Again the notification until will send a message that the diaper has again been wet and what that the resistance values. In the case of the Infant Wireless unit it is deemed that at this point the diaper is saturated and needs to be changed so it will

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periodically notify the caregiver of this and will continue to do so until the diaper is changed and the sensor unit is reset.

The Number of resistances a unit can cycle through is really up to the sensing environment the sensing unit is operating in. The two resistor Wireless infant unit could have very easily had several more resistances giving it a much greater dynamic range. Also the order in which the resistance values are cycled through can also be change, i.e. after the initial wetting the resistance selection algorithm could have left RES_1 on until it triggered for a second time. The possibilities are endless making this a very power full sensing unit.

FIG. 10 shows a rough hand sketch drawing of the algorithm just described above but in a pictoral state machine format. The computer program listing appendix Appendix 1 of this Document contains the VHDL that will run in the Xilinx.

Dynamic Resistance Selecting Rate of Change measuring Based Sensing Technology

This technology tracks the wetness by measuring the voltage across the diaper and only trigger an event if the rate of change of the wetness measure is greater then a threshold value. It also enables that an absolute level be set so that if the rate of change is never detected that it will select another resistance pull up value giving it another dynamic operating range. FIG. 11 illustrates this circuit.

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The adaptive circuit will constantly measure the resistance of the diaper. Converting the resistance of the diaper to a voltage level and sampling the voltage level of this circuit with an Analog to digital converter replaces the comparator sensing circuit. The old comparator based version only returned an absolute value to the sensor event manager, wet or not wet. This new circuit will pass it a voltage value that represents a resistance value. It can use this new value and compare it to the previous sampled value to determine if a wet event has occurred. The threshold value can be set such that small changes in the voltage values will not result in the triggering of a wet event only a large change. This will allow the system to filter out perspiration but still trigger on the wet events.

This unit also has the different pull up resistor allowing the sensor to cycle through them giving the Analog to Digital Converter larger dynamic ranges in which to operate.

The notification system for this circuit can be anything the customer likes. It can include but is not limited to the notification devices discussed in the introduction and implemented in our current device.

The real power of this system and algorithm will be realized when we convert our units from CPLD based controllers to micro controllers that have built in Analog to Digital Comparators.

Microprocessor or ASIC Based Adaptive Sensor Technology

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Eventual replacements of the Xilinx CPLD circuit discussed above will be more cost effective Micro controller based or ASIC based sensor units.

The control algorithms, resistance selection technology and rate of change sampling technology will still be implemented just with a different controller type. FIG. 12 is just one illustration of a microprocessor based sensor unit.

Notification Circuits

Notification of the wet event can include but is not limited to: Blinking LEDs, Voice Record and Playback, Vibration, Buzzer, Melody, and Daycare Software. One embodiment of a remote notification system is the day care monitoring system.

Day Care Monitoring Software

A PC equipped with a Receive antenna tuned to wireless infant units and the Day Care Monitoring software creates a very powerful Notification and Feedback system.

Mommy Wireless Unit

The Mommy unit is Frequencies First Mobile Wireless receiver module. It is tuned to receive messages from the Wireless Infant Units. FIG. 13 is a top level schematic of this unit. It has three feedback mechanisms built into it. They include LED, Buzzer and Vibrator Motor. The unit will receive messages from the Wireless infant unit and based

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on the resistance values encoded into the message will generate a unique feedback to the mother/father of what wet state the diaper is in. The computer program listing appendix has the detailed VHDL software used in operating this circuit.

Caregiver Module

The caregiver module is shown in FIG. 7. It can be implemented in standard handheld and similar computing device. The Caregiver module consists of 12 buttons of services and 12 buttons of observations. It has an on/off switch to conserve power when not being used. It has a send button which is used to initiate a transmission after selecting the appropriate services and/or observations. Any combination of services or observations can be selected. Each of the service and observation buttons is a toggle. Push on and then push off. When one of the observations or services is selected, the associated LED becomes lit. When it is deselected it goes out. When a transmission has been sent, any selected services or observations are blanked out. The module also has a coded serial number. At shift change or when the module is given to another caregiver, the caregiver registers the module serial number during their login. Any transmissions made by that module indicates that caregivers name in the annotated patient history for all care administered. The patient ID is entered by pressing the buttons below the Digital Patient ID display. There is a button for the ones, tens and hundreds columns. Pushing the button below the appropriate digit causes the digit to increment by 1. The digits do not carry over. When a transmission is made from the caregiver module, the patient ID is also transmitted. Each of the services or observations selected in the transmission is annotated to the patient history along with a date/time

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stamp and the caregiver name or ID. The caregiver module also has a visual transmission LED to indicate when a transmission is sent. The core of the caregiver module like the patient module is a xilinx chip. The operation and function of the chip is given in the xilinx module. The caregiver module transmission codes are as follows: The first 4 bits are sync bits. They are hard coded and should be high, low, high, high.

The next 3 bits are ID bits. These bits are what you will use to determine who is sending the data.

001 Patient

010 Caregiver

011 Nurse

100 Physician

When you decode these bits, you will use them to determine which table you will address to decode the remainder of the data in the stream.

The next 9 bits are patient ID bits.

000000001 - will be patient 1. These bits are binary and will be tied to the patient file.

All data in the data stream will be tied to the patient file by way of this identifier.

The next 5 bits are tied to the caregiver modules. They are labeled 1-X where X is the number of modules in a given facility. We will need a key in the software that the facility will press to activate software that will ask who a specific module belongs to.

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00000 is an unassigned value. 00001 would be module 1. If the 3 ID bits above are 001 for the patient, these bits are of no significance. If the 3 ID bits above are 010, the bits will indicate what employee has sent the transmission.

When the employee hits the sign-in key, they will be prompted to enter their name and the module ID. This data will remain set until the next person signs in for that module. All transmissions for that module will be logged with that person as the provider. A database that tracks all of the service rendered by that provider with date needs to be recorded. This would allow the nursing home to monitor the work done by each employee in the facility.

The next 12 bits are the service bits. These bits are not binary. Each bit represents a service.

100000000000	Assisted with transfer
010000000000	Bathed
001000000000	Cleaned Bathroom
000100000000	Bed Made
000010000000	Assisted in Dressing or Hygiene
000001000000	Footcare
000000100000	Incontinence Care
000000010000	Linens Changed
000000001000	Oral Care
000000000100	Showered
000000000010	Therapy

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000000000001 Toileting

Any or all of these bits can be simultaneously transmitted and each service then has to be recorded in the file for the patient ID which accompanied the transmission.

The next 12 bits are the observation bits. These bits are not binary. Each bit represents an observation.

100000000000	Bedsore
010000000000	Bleeding
001000000000	Change in Activity
000100000000	Chest Pain
000010000000	Cold Symptoms
000001000000	Dehydration
000000100000	Depression or Confusion
000000010000	Dizziness
000000001000	Fall
000000000100	Hazard exists
000000000010	Loss of Appetite
000000000001	Nausea or Vomiting

Any or all of these bits can be simultaneously transmitted and each observation then has to be recorded in the file for the patient ID which accompanied the transmission.

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The last 3 bits are end of transmission bits. We should verify, sync and end of transmission bits to be sure we have everything. Each transmission sends the entire bit stream. Only selected bits are 1's and therefore invoke an annotation to the patient history.

Xilinx Chip

The xilinx chip controls all of the inputs and outputs for both the patient module and the caregiver module. It also provides all of the appropriate signal manipulations and processing. It is powered by 2 1.5 volt batteries or one 3V Lithium ION flat battery. The heart of the processing is in that the transmission speed is set by the external clock input into the xilinx chip. This clock determines the rate of the shift registers in shifting out the data to the transmitter. After logic evaluation of appropriate input signals, the data is locked into shift registers. Each of these registers in turn, shifts the bits to the transmit chip. Zeros to clear each register are shifted into the registers upon the start of the send signal. Programming for the xilinx chip is shown at the end of this document.

Diaper

The diaper is an integral part of the patient system and also for the infant system. The purpose of the diaper is to sense an appropriate level of wetness and provide a means of measuring that wetness. The system consists of two metal strips placed in the lining of a diaper. Both the dimension of the strips and distance between the strips are calculated to provide appropriate and uniform resistance changes when they become

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wet with urine. The saline urine forms a resistive link between the strips of metal and this resistance is input into a comparator circuit to produce an appropriate output. The metal used in our application is aluminum because of its cost and ease and variety of manufacture. It has a mylar support backing to provide additional strength during manufacture and application. However, any metal capable of sensing and providing a changing resistance could be also used. Besides the variations in metal, one could also use any conductive fiber which would provide the same function. We have successfully used combination stainless steel and nylon thread in a sewn application which indicates the wide variations capable of providing the same input to the comparator. As far as the diaper goes, it can be disposable or non-disposable and can include any number of materials used in the care of incontinent elderly. The sensing circuitry for the wetness control consists of a resistor divider network on one side of a comparator with the serial input of the diaper on the other. Gnd is supplied on one side of the sensor in the diaper and the other side is connected to the comparator. When wet, the line is pulled to ground with a resistance drop equal to the width of the conductor, separation, and degree of wetness. The comparator resistance is set by generated resistor curves from experimental data. The comparator output feeds into either the patient monitor or in the case of an infant detector, the comparator is embedded into the clip. In the case of the infant detector, the comparator triggers either an audible alarm or a visual LED. See the circuit schematic as shown in FIG. 8.

Diaper Clip

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The diaper clip or diaper contact is a small rectangular PC board with two rows of six pins each angled at about 165-170 degrees (so not quite straight up and down) which have a center point corresponding to the yellow lines(sensor strips) on the diaper liner.

The pins extend slightly through the back of the PC board, such that when they are soldered they will form pin prick contact points. Each of the slightly angled rows will contact one of the aluminum traces on the disposable diaper. The slight angle to the rows will permit the fastener to be slightly off and still contact somewhere on the row of pins.

There is a wire attachment to each of the row of pins so that we can connect these wires to the patient sensor or in the case of the infant diaper sensor, the entire infant module is built on the same pc board and no wires are necessary since it is integrated directly into the sensor module.

Now comes the tricky part. The center of the rectangle, between the 2 rows of solder pin contacts, needs to have a hole drilled to fit a snap. For now it can be a metal snap (the same kind used on clothing. The top of the snap needs to fit flush with the top of the board so that when it is snapped onto the other snap, the two pieces fit snugly. For the finished molded product, the snap will be molded from the plastic used to encase the connector board. I envision that the PC board will be molded directly into the plastic snap which will be shaped like a hinge, having 2 sides as described below. Both sides of the snap or fastener will be molded components and most likely will not be metal as is the prototype.

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The snap will probably have to be epoxyied into the board. Then there needs to be another rectangle of the same dimension which forms the other side of the slip. It needs to have the same hole array, but these holes are left empty so that the soldered point pins can actually go into these holes when the two sides are snapped together. We will work on some kind of a hinge mechanism after we get this part working. This other side will also have a hole drilled into the middle, between the two rows of angled holes which will have the other half of the metal snap epoxyied into it. For the molded finished piece, not the prototype, this second board and female snap will be molded directly into the plastic hinged assembly. For the infant diapers, it will be self contained and will be disposable pretty much. The unit would most likely just be sold with a package of diapers. For the nursing home and assisted living centers, and of course for personal home use, the diaper clip or sensor clip would most likely be associated with a transmitting unit, or patient module.

Here is the way, the whole part will function. The diaper has the two metal strips running down the inside. Where these two strips come up to either the front or the back of the diaper, the plastic liner is folder over on itself, so that the metal strip is exposed on both sides of the diaper (folded over). Over this folded sensor, the clip is placed, one side on one side of the plastic, and the other snap and side on the other side of the plastic. When the two sides are snapped together, it will actually have the plastic liner snapped between the snaps. This will hold the clip firmly onto the diaper, unless it is pulled so hard that the plastic is torn from the liner, with the contact points connecting with the sensor strips in the diaper and transmitting the diaper condition to the modules.

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Xilinx Code For the Patient and Caregiver Module

Addendum to the diaper and diaper sensor used for all applications, both infant, and adult and used in all applications, including wetness sensing, toilet training, and enuresis.

In order to manufacture diapers under assembly line conditions, it is necessary to provide the sensing material in a manner that provides both the electronic sensing capabilities, but also a manner of applying that is cost effective and durable enough to withstand moving assembly line conditions. Prior art deals with the function of this material as wires, and metal, but these are just placed as sensors in the diaper and don't account for the difficulties of manufacturing. Many even suggest in their patents the difficulty of placing these sensors into diapers one by one. This addendum is to clarify the methodology chosen by Frequency to deal with the conditions necessary for manufacturing. Although explained in the prior provisional patent, it was felt that the explanation was not clear enough to remove any doubt of the application and intent and so it will be clarified in this filing.

The metal foil used in this application differs from prior art in that it is a continuous line of sensing film extending the length and width of the diaper depending on the application and the equipment being used. It is a laminated film of metal, in this case aluminum, and a backing which provides both tensile strength and permeability. The ideal application is a laminate that is perforated or porous providing both strength, and

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insulation. This sensing layer is placed in the diaper at any level considered applicable, but would be most appropriate beneath the absorbent pad and exterior impermeable layer. There are some applications where it would be appropriate to contact this sensing strip from the exterior of the diaper. In order to do this, the strip would run past a location in the exterior of the diaper where holes have been placed in the layer providing electrical contact exterior to the diaper. Where clips or other mechanical connectors are used, these holes are not necessary and the clip or mechanical device provides sufficient contact to the strip conductors. These strip conductors can but do not need to be adhesive coated. The manufacturing flow of the diaper places sufficient adhesive into the diaper lining to provide the necessary adhesion for the sensing strips. In this manner, these strips match very well with existing processing flows.

In the prior filing we indicated that we had done trials on a stainless steel thread that could be sewn into a sensing pattern or substrate. It could just as easily be placed into the assembly line like the metal foils described above without any necessity for sewing. It could also be multidirectional depending on the sophistication of the assembly line equipment.

The actual attachments of the electronics to the sensing strips is by standard electrical contact methods and is outside the scope of this filing. Suffice it to say that all types of connectors may be utilized including but not limited to: snaps, clips, direct solder, fusion, friction bonding, surface contacts, puncture, and stitched and could include any combination of connections such as snaps and stitched.

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Sensing Electronics

This filing will also describe improved methodologies for the electronics used in sensing wetness. One of the inherent problems with sensing wetness is the wide range of wet conditions. These are caused from differences in habitation (humid areas verses dry), activity, differences in body types, living conditions, etc. Sweat is a major cause of problems giving inconsistent readings, false readings, etc. These differences are why no system is currently on the market because no product developed to date has been capable of giving 100% accuracy.

Our methodology is significantly different from any prior art. Prior art uses a resistivity threshold trigger, a capacitance change, etc. Our embodiment determines a baseline and then consistently monitors that baseline making realtime corrections until an event occurs that is a large enough change from this realtime baseline to be considered a valid state change (wet condition). This concept of establishing a baseline and then continuing realtime monitoring and changes to that baseline until an event occurs is novel.

The baseline is established by a automated routine which the electronics performs when the diaper is attached to the electronics. This baseline is monitored on a preprogrammed interval which can adapt and change depending on realtime changes which are occurring. In otherwords, the system is a smart monitor capable of sensing and adapting its readings to realtime baseline changes. These realtime baseline changes allow for resistance changes without giving false readings that a wetness event

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has occurred. Only when the realtime delta exceeds a predetermined step function does the system recognize a wet event.

All known embodiments of notification when a wetness event occurs would then be applicable. These are already established electronics and are prior art. They would include but not be limited to the following: LED, buzzer, beeper, alarm, wireless transmission, wired transmission, pizzo, modem, direct internet connection, etc.

This methodology can be local in the diaper or medium where wetness is being measured or can be remotely transmitted data that is processed by an algorithm located on an external device. Two example of the electronics used in this application is shown below along with a sketch of the algorithm state machine.

While the invention has been described in connection with a preferred embodiment, it is not intended to limit the scope of the invention to the particular form set forth, but on the contrary, it is intended to cover such alternatives, modifications, and equivalents as may be included within the spirit and scope of the invention as defined by the appended claims.

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Appendix A: Computer Program Listing Appendix

CARE GIVER CODE:

Care_giver_top.vhd

```

library IEEE;
use IEEE.STD_LOGIC_1164.ALL;
use IEEE.STD_LOGIC_ARITH.ALL;
use IEEE.STD_LOGIC_UNSIGNED.ALL;

-- Uncomment the following lines to use the declarations that are
-- provided for instantiating Xilinx primitive components.
--library UNISIM;
--use UNISIM.VComponents.all;

entity care_giver_top is
  Port ( Reset : in std_logic;
        Clk : in std_logic;
        Send : in std_logic;
        Key_Pad_Row : in std_logic_vector(3 downto 0);
        Key_Pad_Column : in std_logic_vector(5 downto 0);
        Patient_ID_hundreds : in std_logic;
        Patient_ID_tens : in std_logic;
        Patient_ID_ones : in std_logic;
        Tx_Data : out std_logic;
        Tx_EN : out std_logic;
        Key_Pad_LED : out std_logic_vector(23 downto 0);
        Patient_ID_hundreds_Seg : out std_logic;
        Patient_ID_tens_Seg : out std_logic_vector(6 downto 0);
        Patient_ID_ones_Seg : out std_logic_vector(6 downto 0));
end care_giver_top;

architecture RTL of care_giver_top is

  component key_pad_decode_small is
    Port ( Clk : in std_logic;
          Chip_Reset : in std_logic;
          Keypad_Row : in std_logic_vector(3 downto 0);
          Keypad_Column : in std_logic_vector(5 downto 0);
          Send_Reset : in std_logic;
          Keypad_transmit : out std_logic_vector(23 downto 0));
  end component;

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component patient_ID_decode is
  Port ( Chip_Reset : in std_logic;
        Clk : in std_logic;
        Patient_ID_hundreds : in std_logic;
        Patient_ID_tens : in std_logic;
        Patient_ID_ones : in std_logic;
        Patient_ID_hundreds_Seg : out std_logic;
        Patient_ID_tens_Seg : out std_logic_vector(6 downto 0);
        Patient_ID_ones_Seg : out std_logic_vector(6 downto 0);
        Patient_ID_transmit : out std_logic_vector(8 downto 0));
end component;

```

```

component transmit_data_small is
  Port ( Chip_Reset : in std_logic;
        Clk : in std_logic;
        Send : in std_logic;
        Keypad_transmit : in std_logic_vector(23 downto 0);
        Patient_ID_transmit : in std_logic_vector(8 downto 0);
        Tx_EN : out std_logic;
        Tx_Data : out std_logic;
        Send_Reset : out std_logic);
end component;

```

```

signal Send_Reset : std_logic;
signal Keypad_transmit_int : std_logic_vector(0 to 23);
signal Patient_ID_transmit : std_logic_vector(8 downto 0);

```

```

begin

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```

  Key_Pad_LED <= Keypad_transmit_int;

```

```

  key_dec : key_pad_decode_small
  Port Map ( Clk => Clk,
            Chip_Reset => Reset,
            Keypad_Row => Key_Pad_Row,
            Keypad_Column => Key_Pad_Column,
            Send_Reset => Send_Reset,
            Keypad_transmit => Keypad_transmit_int);

```

```

  pat_ID : patient_ID_decode
  Port Map ( Chip_Reset => Reset,
            Clk => Clk,
            Patient_ID_hundreds => Patient_ID_hundreds,
            Patient_ID_tens => Patient_ID_tens,

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    Patient_ID_ones => Patient_ID_ones,
    Patient_ID_hundreds_Seg => Patient_ID_hundreds_Seg,
    Patient_ID_tens_Seg => Patient_ID_tens_Seg,
    Patient_ID_ones_Seg => Patient_ID_ones_Seg,
    Patient_ID_transmit => Patient_ID_transmit);

trans_data : transmit_data_small
    Port Map ( Chip_Reset => Reset,
              Clk => Clk,
              Send => Send,
              Keypad_transmit => Keypad_transmit_int,
              Patient_ID_transmit => Patient_ID_transmit,
              Tx_EN => Tx_EN,
              Tx_Data => Tx_Data,
              Send_Reset => Send_Reset);

```

```

end RTL;

```

```

keypad_decode.vhd

```

```

library IEEE;
use IEEE.STD_LOGIC_1164.ALL;
use IEEE.STD_LOGIC_ARITH.ALL;
use IEEE.STD_LOGIC_UNSIGNED.ALL;

-- Uncomment the following lines to use the declarations that are
-- provided for instantiating Xilinx primitive components.
--library UNISIM;
--use UNISIM.VComponents.all;

entity key_pad_decode_small is
    Port (Clk : in std_logic;
          Chip_Reset : in std_logic;
          Keypad_Row : in std_logic_vector(3 downto 0);
          Keypad_Column : in std_logic_vector(5 downto 0);
          Send_Reset : in std_logic;
          Keypad_transmit : out std_logic_vector(0 to 23));
end key_pad_decode_small;

architecture RTL of key_pad_decode_small is
    type STATE_TYPE is (S0, S1, S2, S3);
    signal current_state, next_state : STATE_TYPE;

    signal Keypad_Row_Q1 : std_logic_vector(3 downto 0);
    signal Keypad_Column_Q1 : std_logic_vector(5 downto 0);

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signal Keypad_Row_Q2 : std_logic_vector(3 downto 0);
signal Keypad_Column_Q2 : std_logic_vector(5 downto 0);
--signal Keypad_Row_Q3 : std_logic_vector(3 downto 0);
--signal Keypad_Column_Q3 : std_logic_vector(5 downto 0);
--signal Keypad_Row_Debounce : std_logic_vector(3 downto 0);
--signal Keypad_Column_Debounce : std_logic_vector(5 downto 0);

signal Keypad_lat_EN : natural range 0 to 24;
signal Keypad_transmit_int : std_logic_vector(23 downto 0);

begin

Keypad_transmit <= Keypad_transmit_int;

--Debounce the input key pad
key_dbounce : process(Chip_Reset, Clk) IS
begin
    if(Chip_Reset = '0') then
        Keypad_Row_Q1 <= (others => '1');
        Keypad_Column_Q1 <= (others => '1');
        Keypad_Row_Q2 <= (others => '1');
        Keypad_Column_Q2 <= (others => '1');
        --Keypad_Row_Q3 <= (others => '1');
        --Keypad_Column_Q3 <= (others => '1');
    elsif(rising_edge(clk)) then
        Keypad_Row_Q1 <= Keypad_Row;
        Keypad_Column_Q1 <= Keypad_Column;
        Keypad_Row_Q2 <= Keypad_Row_Q1;
        Keypad_Column_Q2 <= Keypad_Column_Q1;
        --Keypad_Row_Q3 <= Keypad_Row_Q2;
        --Keypad_Column_Q3 <= Keypad_Column_Q2;
    end if;
end process;

--Keypad_Row_Debounce <= not((Keypad_Row_Q1 or Keypad_Row_Q2) or
Keypad_Row_Q3);
--Keypad_Column_Debounce <= not((Keypad_Column_Q1 or Keypad_Column_Q2) or
Keypad_Column_Q3);

--Decode Row Column
RC_decode : process(Keypad_Row_Q2, Keypad_Column_Q2) IS
begin
    case Keypad_Column_Q2 Is
        when "011111" =>
            if(Keypad_Row_Q2 = "0111") then
                Keypad_lat_EN <= 1;
            end if;
        when others =>
            Keypad_lat_EN <= 0;
    end case;
end process;

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elseif(Keypad_Row_Q2 = "1011") then
    Keypad_lat_EN <= 7;
elseif(Keypad_Row_Q2 = "1101") then
    Keypad_lat_EN <= 13;
elseif(Keypad_Row_Q2 = "1110") then
    Keypad_lat_EN <= 19;
else
    Keypad_lat_EN <= 0;
end if;
when "101111" =>
    if(Keypad_Row_Q2 = "0111") then
        Keypad_lat_EN <= 2;
    elseif(Keypad_Row_Q2 = "1011") then
        Keypad_lat_EN <= 8;
    elseif(Keypad_Row_Q2 = "1101") then
        Keypad_lat_EN <= 14;
    elseif(Keypad_Row_Q2 = "1110") then
        Keypad_lat_EN <= 20;
    else
        Keypad_lat_EN <= 0;
    end if;
when "110111" =>
    if(Keypad_Row_Q2 = "0111") then
        Keypad_lat_EN <= 3;
    elseif(Keypad_Row_Q2 = "1011") then
        Keypad_lat_EN <= 9;
    elseif(Keypad_Row_Q2 = "1101") then
        Keypad_lat_EN <= 15;
    elseif(Keypad_Row_Q2 = "1110") then
        Keypad_lat_EN <= 21;
    else
        Keypad_lat_EN <= 0;
    end if;
when "111011" =>
    if(Keypad_Row_Q2 = "0111") then
        Keypad_lat_EN <= 4;
    elseif(Keypad_Row_Q2 = "1011") then
        Keypad_lat_EN <= 10;
    elseif(Keypad_Row_Q2 = "1101") then
        Keypad_lat_EN <= 16;
    elseif(Keypad_Row_Q2 = "1110") then
        Keypad_lat_EN <= 22;
    else
        Keypad_lat_EN <= 0;
    end if;
when "111101" =>

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        if(Keypad_Row_Q2 = "0111") then
            Keypad_lat_EN <= 5;
        elsif(Keypad_Row_Q2 = "1011") then
            Keypad_lat_EN <= 11;
        elsif(Keypad_Row_Q2 = "1101") then
            Keypad_lat_EN <= 17;
        elsif(Keypad_Row_Q2 = "1110") then
            Keypad_lat_EN <= 23;
        else
            Keypad_lat_EN <= 0;
        end if;
    when "111110" =>
        if(Keypad_Row_Q2 = "0111") then
            Keypad_lat_EN <= 6;
        elsif(Keypad_Row_Q2 = "1011") then
            Keypad_lat_EN <= 12;
        elsif(Keypad_Row_Q2 = "1101") then
            Keypad_lat_EN <= 18;
        elsif(Keypad_Row_Q2 = "1110") then
            Keypad_lat_EN <= 24;
        else
            Keypad_lat_EN <= 0;
        end if;
    when others =>
        Keypad_lat_EN <= 0;
    end case;
end process;

--RC decode State CNTL

cur_state : process (Chip_Reset, Clk) IS
begin
    if(Chip_Reset = '0') then
        current_state <= S0;
    elsif (rising_edge(Clk)) then
        current_state <= next_state;
    end if;
end process cur_state;

comb_logic : process (Keypad_Row_Q2, current_state) IS
begin
    case current_state IS
        when S0 => --RC detected State
            --if(Keypad_Row_Debounce(3) = '1' or
            Keypad_Row_Debounce(2) = '1' or

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--Keypad_Row_Debounce(1) = '1' or
Keypad_Row_Debounce(0) = '1' or
--Keypad_Column_Debounce(5) = '1' or
Keypad_Column_Debounce(4) = '1' or
--Keypad_Column_Debounce(3) = '1' or
Keypad_Column_Debounce(2) = '1' or
--Keypad_Column_Debounce(1) = '1' or
Keypad_Column_Debounce(0) = '1' ) then
    if(Keypad_Row_Q2(3) = '0' or Keypad_Row_Q2(2) = '0' or
Keypad_Row_Q2(1) = '0' or Keypad_Row_Q2(0) = '0') then
        --Keypad_Column_Q2(5) = '1' or Keypad_Column_Q2(4) = '1'
or
        --Keypad_Column_Q2(3) = '1' or Keypad_Column_Q2(2) = '1'
or
        --Keypad_Column_Q2(1) = '1' or Keypad_Column_Q2(0) = '1' )
    then
        next_state <= S1;
    else
        next_state <= S0;
    end if;
when S1 => --Decode Wait State
    next_state <= S2;
when S2 => -- Read RC Decode and generate enables
    next_state <= S3;
when S3 => --Read RC Decode and generate enables
    -- Wait for RC to reset back to initial value
    if(Keypad_Row_Q2(3) = '0' or Keypad_Row_Q2(2) = '0' or
Keypad_Row_Q2(1) = '0' or Keypad_Row_Q2(0) = '0') then
        --Keypad_Column_Q2(5) = '1' or Keypad_Column_Q2(4) = '1'
or
        --Keypad_Column_Q2(3) = '1' or Keypad_Column_Q2(2) = '1'
or
        --Keypad_Column_Q2(1) = '1' or Keypad_Column_Q2(0) = '1' )
    then
        next_state <= S3;
    else
        next_state <= S0;
    end if;
when others =>
    next_state <= S0;
end case;
end process comb_logic;

lat_keys : process (Chip_Reset, Send_Reset, Clk) IS
begin
    if(Chip_Reset = '0' or Send_Reset = '1') then

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        Keypad_transmit_int <= (others => '0');
    elsif(rising_edge(Clk)) then
        if(current_state = S2) then
            if(Keypad_lat_EN = 1) then
                Keypad_transmit_int(0) <= not Keypad_transmit_int(0);
            end if;

            if(Keypad_lat_EN = 2) then
                Keypad_transmit_int(1) <= not Keypad_transmit_int(1);
            end if;

            if(Keypad_lat_EN = 3) then
                Keypad_transmit_int(2) <= not Keypad_transmit_int(2);
            end if;

            if(Keypad_lat_EN = 4) then
                Keypad_transmit_int(3) <= not Keypad_transmit_int(3);
            end if;
            if(Keypad_lat_EN = 5) then
                Keypad_transmit_int(4) <= not Keypad_transmit_int(4);
            end if;

            if(Keypad_lat_EN = 6) then
                Keypad_transmit_int(5) <= not Keypad_transmit_int(5);
            end if;

            if(Keypad_lat_EN = 7) then
                Keypad_transmit_int(6) <= not Keypad_transmit_int(6);
            end if;

            if(Keypad_lat_EN = 8) then
                Keypad_transmit_int(7) <= not Keypad_transmit_int(7);
            end if;
            if(Keypad_lat_EN = 9) then
                Keypad_transmit_int(8) <= not Keypad_transmit_int(8);
            end if;

            if(Keypad_lat_EN = 10) then
                Keypad_transmit_int(9) <= not Keypad_transmit_int(9);
            end if;

            if(Keypad_lat_EN = 11) then
                Keypad_transmit_int(10) <= not Keypad_transmit_int(10);
            end if;

            if(Keypad_lat_EN = 12) then

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    Keypad_transmit_int(11) <= not Keypad_transmit_int(11);
end if;
if(Keypad_lat_EN = 13) then
    Keypad_transmit_int(12) <= not Keypad_transmit_int(12);
end if;

if(Keypad_lat_EN = 14) then
    Keypad_transmit_int(13) <= not Keypad_transmit_int(13);
end if;

if(Keypad_lat_EN = 15) then
    Keypad_transmit_int(14) <= not Keypad_transmit_int(14);
end if;

if(Keypad_lat_EN = 16) then
    Keypad_transmit_int(15) <= not Keypad_transmit_int(15);
end if;
if(Keypad_lat_EN = 17) then
    Keypad_transmit_int(16) <= not Keypad_transmit_int(16);
end if;

if(Keypad_lat_EN = 18) then
    Keypad_transmit_int(17) <= not Keypad_transmit_int(17);
end if;

if(Keypad_lat_EN = 19) then
    Keypad_transmit_int(18) <= not Keypad_transmit_int(18);
end if;

if(Keypad_lat_EN = 20) then
    Keypad_transmit_int(19) <= not Keypad_transmit_int(19);
end if;
if(Keypad_lat_EN = 21) then
    Keypad_transmit_int(20) <= not Keypad_transmit_int(20);
end if;

if(Keypad_lat_EN = 22) then
    Keypad_transmit_int(21) <= not Keypad_transmit_int(21);
end if;

if(Keypad_lat_EN = 23) then
    Keypad_transmit_int(22) <= not Keypad_transmit_int(22);
end if;

if(Keypad_lat_EN = 24) then
    Keypad_transmit_int(23) <= not Keypad_transmit_int(23);

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        end if;

        end if;
    end if;

end process lat_keys;

end RTL;

patient_id_decode.vhd

library IEEE;
use IEEE.STD_LOGIC_1164.ALL;
use IEEE.STD_LOGIC_ARITH.ALL;
use IEEE.STD_LOGIC_UNSIGNED.ALL;

-- Uncomment the following lines to use the declarations that are
-- provided for instantiating Xilinx primitive components.
--library UNISIM;
--use UNISIM.VComponents.all;

entity patient_ID_decode is
    Port ( Chip_Reset : in std_logic;
          Clk : in std_logic;
          Patient_ID_hundreds : in std_logic;
          Patient_ID_tens : in std_logic;
          Patient_ID_ones : in std_logic;
          Patient_ID_hundreds_Seg : out std_logic;
          Patient_ID_tens_Seg : out std_logic_vector(6 downto 0);
          Patient_ID_ones_Seg : out std_logic_vector(6 downto 0);
          Patient_ID_transmit : out std_logic_vector(8 downto 0));
end patient_ID_decode;

architecture RTL of patient_ID_decode is

    signal Patient_ID_hundreds_Q1 : std_logic;
    signal Patient_ID_tens_Q1 : std_logic;
    signal Patient_ID_ones_Q1 : std_logic;
    signal Patient_ID_hundreds_Q2 : std_logic;
    signal Patient_ID_tens_Q2 : std_logic;
    signal Patient_ID_ones_Q2 : std_logic;
    signal Patient_ID_hundreds_Q3 : std_logic;
    signal Patient_ID_tens_Q3 : std_logic;
    signal Patient_ID_ones_Q3 : std_logic;

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signal Patient_ID_hundreds_Debounce : std_logic;
signal Patient_ID_tens_Debounce : std_logic;
signal Patient_ID_ones_Debounce : std_logic;

signal hundreds_count : std_logic;
signal tens_count: std_logic_vector(3 downto 0);
signal ones_count: std_logic_vector(3 downto 0);

begin

--Debounce
pat_ID_debounce : process (Chip_Reset, Clk) IS
Begin
    iff(Chip_Reset = '0') then
        Patient_ID_hundreds_Q1 <= '0';
        Patient_ID_tens_Q1 <= '0';
        Patient_ID_ones_Q1 <= '0';
        Patient_ID_hundreds_Q2 <= '0';
        Patient_ID_tens_Q2 <= '0';
        Patient_ID_ones_Q2 <= '0';
        Patient_ID_hundreds_Q3 <= '0';
        Patient_ID_tens_Q3 <= '0';
        Patient_ID_ones_Q3 <= '0';
    elsif(Rising_edge(Clk)) then
        Patient_ID_hundreds_Q1 <= Patient_ID_hundreds;
        Patient_ID_tens_Q1 <= Patient_ID_tens;
        Patient_ID_ones_Q1 <= Patient_ID_ones;
        Patient_ID_hundreds_Q2 <= Patient_ID_hundreds_Q1;
        Patient_ID_tens_Q2 <= Patient_ID_tens_Q1;
        Patient_ID_ones_Q2 <= Patient_ID_ones_Q1;
        Patient_ID_hundreds_Q3 <= Patient_ID_hundreds_Q2;
        Patient_ID_tens_Q3 <= Patient_ID_tens_Q2;
        Patient_ID_ones_Q3 <= Patient_ID_ones_Q2;
    end if;
end process;

Patient_ID_hundreds_Debounce <= not(Patient_ID_hundreds_Q1) and
not(Patient_ID_hundreds_Q2) and Patient_ID_hundreds_Q3;
Patient_ID_tens_Debounce <= not(Patient_ID_tens_Q1) and not(Patient_ID_tens_Q2)
and Patient_ID_tens_Q3;
Patient_ID_ones_Debounce <= not(Patient_ID_ones_Q1) and not(Patient_ID_ones_Q2)
and Patient_ID_ones_Q3;

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-- hundreds counter
hun : process(Chip_Reset, Clk) IS
begin
    if(Chip_Reset = '0') then
        hundreds_count <= '0';
    elsif(rising_edge(Clk)) then
        if(Patient_ID_hundreds_Debounce = '1') then
            hundreds_count <= not hundreds_count;
        end if;
    end if;
end process;

tens : process(Chip_Reset, Clk) IS
begin
    if(Chip_Reset = '0') then
        tens_count <= "0000";
    elsif(rising_edge(Clk)) then
        if(Patient_ID_tens_Debounce = '1') then
            if(tens_count >= "1001") then
                tens_count <= "0000";
            else
                tens_count <= tens_count + '1';
            end if;
        end if;
    end if;
end process;

ones : process(Chip_Reset, Clk) IS
begin
    if(Chip_Reset = '0') then
        ones_count <= "0000";
    elsif(rising_edge(Clk)) then
        if(Patient_ID_ones_Debounce = '1') then
            if(ones_count >= "1001") then
                ones_count <= "0000";
            else
                ones_count <= tens_count + '1';
            end if;
        end if;
    end if;
end process;

--Encode Patient ID for 7 Seg displays and 9 bit patient ID

--This is how the Patient ID is writtent out in the current sch.
--The BCD value is transmitted with the msb of the ones count being shifted out first.

```

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```

Patient_ID_transmit <= ones_count & tens_count & hundreds_count;

Patient_ID_hundreds_Seg <= hundreds_count;
--huns_seg : process(Chip_Reset, hundreds_count) IS
--begin
--    case hundreds_count is
--        when '0' => Patient_ID_hundreds_Seg <= "0000000"; -- 0
--        when '1' => Patient_ID_hundreds_Seg <= "0000000"; -- 1
--        when others => Patient_ID_hundreds_Seg <= "0000000"; -- 0
--    end case;

--end process huns_seg;

tens_seg : process(Chip_Reset, tens_count) IS
begin
    case tens_count is
        when X"0" => Patient_ID_tens_Seg <= "1111011"; -- 0
        when X"1" => Patient_ID_tens_Seg <= "1100000"; -- 1
        when X"2" => Patient_ID_tens_Seg <= "0110111"; -- 2
        when X"3" => Patient_ID_tens_Seg <= "1110101"; -- 3
        when X"4" => Patient_ID_tens_Seg <= "1101100"; -- 4
        when X"5" => Patient_ID_tens_Seg <= "1011101"; -- 5
        when X"6" => Patient_ID_tens_Seg <= "1011111"; -- 6
        when X"7" => Patient_ID_tens_Seg <= "1110000"; -- 7
        when X"8" => Patient_ID_tens_Seg <= "1111111"; -- 8
        when X"9" => Patient_ID_tens_Seg <= "1111100"; -- 9
        when others => Patient_ID_tens_Seg <= "1111011"; -- 0
    end case;

end process tens_seg;

ones_seg : process(Chip_Reset, ones_count) IS
begin
    case ones_count is
        when X"0" => Patient_ID_ones_Seg <= "1011111"; -- 0
        when X"1" => Patient_ID_ones_Seg <= "0000110"; -- 1
        when X"2" => Patient_ID_ones_Seg <= "0111011"; -- 2
        when X"3" => Patient_ID_ones_Seg <= "0101111"; -- 3
        when X"4" => Patient_ID_ones_Seg <= "1100110"; -- 4
        when X"5" => Patient_ID_ones_Seg <= "1101101"; -- 5
        when X"6" => Patient_ID_ones_Seg <= "1111101"; -- 6
        when X"7" => Patient_ID_ones_Seg <= "0000111"; -- 7
        when X"8" => Patient_ID_ones_Seg <= "1111111"; -- 8
        when X"9" => Patient_ID_ones_Seg <= "1100111"; -- 9
        when others => Patient_ID_ones_Seg <= "1011111"; -- 0
    end case;

```


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```
end process ones_seg;
```

```
end RTL;
```

```
transmit_data.vhd
```

```
library IEEE;
```

```
use IEEE.STD_LOGIC_1164.ALL;
```

```
use IEEE.STD_LOGIC_ARITH.ALL;
```

```
use IEEE.STD_LOGIC_UNSIGNED.ALL;
```

```
-- Uncomment the following lines to use the declarations that are
```

```
-- provided for instantiating Xilinx primitive components.
```

```
--library UNISIM;
```

```
--use UNISIM.VComponents.all;
```

```
entity transmit_data_small is
```

```
  Port ( Chip_Reset : in std_logic;
```

```
        Clk : in std_logic;
```

```
        Send : in std_logic;
```

```
        Keypad_transmit : in std_logic_vector(23 downto 0);
```

```
        Patient_ID_transmit : in std_logic_vector(8 downto 0);
```

```
        Tx_EN : out std_logic;
```

```
        Tx_Data : out std_logic;
```

```
        Send_Reset : out std_logic);
```

```
end transmit_data_small;
```

```
architecture RTL of transmit_data_small is
```

```
  type STATE_TYPE is (S0, S1, S2, S3, S4);
```

```
  signal current_state, next_state : STATE_TYPE;
```

```
  -- Transmit Enable internal Signal
```

```
  signal Transmit_EN_int : std_logic;
```

```
  signal shift_register : std_logic_vector(51 downto 0);
```

```
  signal shift_count : natural range 0 to 52;
```

```
  signal send_Q1 : std_logic;
```

```
  signal send_Q2 : std_logic;
```

```
  signal send_Q3 : std_logic;
```

```
  signal send_debounce : std_logic;
```

```
  --signal send_lat : std_logic;
```

```
  constant Sync_Fill : std_logic_vector(3 downto 0) := "0000";
```

```
  constant Sync_Pattern : std_logic_vector(3 downto 0) := "1011";
```

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```

constant System_ID : std_logic_vector(2 downto 0) := "100";
--constant Patient_ID : std_logic_vector(8 downto 0) := "100000000";
constant Pendant_ID : std_logic_vector(4 downto 0) := "10000";
--constant Fill_Pattern : std_logic_vector(15 downto 0) := X"0000";
constant End_Pattern : std_logic_vector(2 downto 0) := "010";

begin

-- OUTPUT Concurrent Signals
-- Transmit enable
Tx_EN <= '0' when Chip_Reset = '0' else Transmit_EN_int when rising_edge(Clk);
-- Shift Data OUT
Tx_Data <= shift_register(51);

--Debounce Send
pat_ID_debounce : process (Chip_Reset, Clk) IS
Begin
    if(Chip_Reset = '0') then
        send_Q1 <= '0';
        send_Q2 <= '0';
        send_Q3 <= '0';

        elsif(Rising_edge(Clk)) then
            send_Q1 <= send;
            send_Q2 <= send_Q1;
            send_Q3 <= send_Q2;

        end if;
    end process;

    send_Debounce <= not(send_Q1) and not(send_Q2) and send_Q3;

--sen_lat : process(Clk, Chip_Reset) is
--begin
--    if(Chip_Reset = '0') then
--        send_lat <= '0';
--    elsif(rising_edge(Clk)) then
--        if(current_state = S3) then
--            send_lat <= '0';
--        elsif(send_Debounce = '1') then
--            send_lat <= '1';
--        end if;
--    end if;
--end process sen_lat;

```

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```

cur_state : process (Chip_Reset, Clk) IS
begin
    if(Chip_Reset = '0') then
        current_state <= S0;
    elsif (rising_edge(Clk)) then
        current_state <= next_state;
    end if;
end process cur_state;

comb_logic : process (current_state, send_Debounce, shift_count)
begin
    case current_state is
        when S0 =>
            -- outputs
            Transmit_EN_int <= '0';

            --next state
            if(send_Debounce = '1') then
                next_state <= S1;
            else
                next_state <= S0;
            end if;
        when S1 =>
            Transmit_EN_int <= '1';
            next_state <= S2;
        when S2 =>
            Transmit_EN_int <= '1';
            next_state <= S3;
        when S3 =>
            Transmit_EN_int <= '1';
            next_state <= S2;
            if(shift_count < 51) then
                next_state <= S3;
            else
                next_state <= S4;
            end if;
        when S4 =>
            Transmit_EN_int <= '0';
            next_state <= S0;
        when others =>
            Transmit_EN_int <= '0';
            next_state <= S0;
    end case;
end process comb_logic;

```

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```

shift_reg : process (Clk, Chip_RESET ) IS
begin
    if(Chip_RESET = '0') then
        shift_register <= (others => '0');
    elsif(rising_edge(Clk)) then
        if (current_state = S1) then
            shift_register <= Sync_Fill & Sync_Pattern & System_ID &
                Patient_ID_transmit & Pendant_ID &
                Keypad_transmit & End_Pattern;
        elsif (current_state = S3) then
            shift_register <= shift_register(50 downto 0) & '0';
        end if;
    end if;

end process shift_reg;

shift_cnt : process ( Clk, Chip_RESET) IS
begin
    if(Chip_RESET = '0') then
        shift_count <= 0;
    elsif( rising_edge(Clk)) then
        if(current_state = S3) then
            shift_count <= shift_count + 1;
        else
            shift_count <= 0;
        end if;
    end if;

end process shift_cnt;

send_rst : process (Clk, Chip_RESET) IS
begin
    if(Chip_RESET = '0') then
        Send_Reset <= '0';
    elsif(rising_edge(Clk)) then
        if (current_state = S4 ) then
            Send_Reset <= '1';
        else
            Send_Reset <= '0';
        end if;
    end if;

end process send_rst;

end RTL;

```

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Wireless Infant Module VHDL

```

library IEEE;
use IEEE.STD_LOGIC_1164.ALL;
use IEEE.STD_LOGIC_ARITH.ALL;
use IEEE.STD_LOGIC_UNSIGNED.ALL;

-- Uncomment the following lines to use the declarations that are
-- provided for instantiating Xilinx primitive components.
--library UNISIM;
--use UNISIM.VComponents.all;

entity infant_wireless is
  Port (
    po_reset_n          : IN STD_LOGIC;
    button_reset_n      : IN STD_LOGIC;
    clk_64khz           : IN STD_LOGIC;
    wet                  : IN STD_LOGIC;

    res1                 : OUT STD_LOGIC;
    res2                 : OUT STD_LOGIC;
    tx_data              : OUT STD_LOGIC;
    lm_555_pwr           : OUT STD_LOGIC
  );
end infant_wireless;

architecture rtl of infant_wireless is

  type STATE_TYPE is (WET_WAIT, WET_DETECT, SEND, CH_RES, SETTLE);
  signal current_state, next_state : STATE_TYPE;

  CONSTANT SYNC_PATTERN   : STD_LOGIC_VECTOR(4 DOWNTO 0) :=
    "01011";
  CONSTANT INFANT_ID      : STD_LOGIC_VECTOR(14 DOWNTO 0) :=
    X"CCC" & B"111"; -- Patient Number = 4
  CONSTANT END_PATTERN    : STD_LOGIC_VECTOR(1 DOWNTO 0) := "01";

  CONSTANT WET_STATE      : STD_LOGIC := '1';
  CONSTANT MESSAGE_SENT   : STD_LOGIC_VECTOR(4 DOWNTO 0) :=
    B"1_0110";

  CONSTANT MSB_SETTLE     : NATURAL := 17;

  CONSTANT LOAD_SEC       : STD_LOGIC_VECTOR(3 DOWNTO 0)
    := "0111";

```

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```

CONSTANT LOAD_THIRD      : STD_LOGIC_VECTOR(3 DOWNTO 0) :=
"1111";

SIGNAL wet_lat : STD_LOGIC;
SIGNAL wet_lat2 : STD_LOGIC;

SIGNAL shift_register      : STD_LOGIC_VECTOR(7 downto 0);
SIGNAL reset_n              : STD_LOGIC;
--SIGNAL lm555_pwr          : STD_LOGIC;

SIGNAL clk                  : STD_LOGIC;
SIGNAL clk_1khz             : STD_LOGIC;
SIGNAL clk_1khz_cnt         : STD_LOGIC_VECTOR(4 DOWNTO 0);

SIGNAL settle_count        : STD_LOGIC_VECTOR(MSB_SETTLE DOWNTO 0);

SIGNAL res_sel_cnt          : STD_LOGIC_VECTOR(1 DOWNTO 0);
SIGNAL res_sel_send        : STD_LOGIC_VECTOR(1 DOWNTO 0);
SIGNAL saturation          : STD_LOGIC;

```

BEGIN

reset_n <= po_reset_n and button_reset_n;

lm_555_pwr <= '1';

tx_data <= shift_register(7);

--CLOCK GENERATION

clk <= clk_1khz;

one_khz_clk : PROCESS(clk_64khz, reset_n)

BEGIN

IF (reset_n = '0') THEN

clk_1khz <= '0';

clk_1khz_cnt <= "00000";

ELSIF(RISING_EDGE(clk_64kHz)) THEN

clk_1khz_cnt <= clk_1khz_cnt + '1';

IF(clk_1khz_cnt = "11111") THEN

clk_1khz <= not clk_1khz;

END IF;

END IF;

END PROCESS;

-- DeBounce Latches

dbounce : process (clk, reset_n) IS

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```

begin
    if(reset_n = '0') then

        wet_lat <= '0';
        wet_lat2 <= '0';

        elsif(rising_edge(Clk)) then

            wet_lat <= wet;
            wet_lat2 <= wet_lat;
        end if;
    end process dbounce;

    -- Debounce incoming signals
    --Visit_IN_debounce <= '1' when (Visit_IN_Q1 = '0' and Visit_IN_Q2 = '0' and
    Visit_IN_Q3 = '1') else '0';

    cur_state : PROCESS (reset_n, clk) IS
    BEGIN
        IF(reset_n = '0') then
            current_state <= WET_WAIT;
        ELSIF (RISING_EDGE(clk)) THEN
            current_state <= next_state;
        END IF;
    END PROCESS cur_state;

    nxt_state : PROCESS (current_state, wet_lat2, settle_count, saturation)
    BEGIN
        CASE current_state is
            WHEN WET_WAIT =>
                --next state
                IF(wet_lat2 = WET_STATE or saturation = '1') THEN
                    next_state <= WET_DETECT;
                ELSE
                    next_state <= WET_WAIT;
                END IF;
            WHEN WET_DETECT =>
                next_state <= SEND;
            WHEN SEND =>
                IF(settle_count(4 DOWNT0 0) = MESSAGE_SENT) THEN
                    next_state <= CH_RES;
                ELSE
                    next_state <= SEND;
                END IF;
        END CASE;
    END PROCESS;

```

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```

        WHEN CH_RES =>
            next_state <= SETTLE;
        WHEN SETTLE =>
            IF(settle_count(MSB_SETTLE) = '1') THEN
                next_state <= WET_WAIT;
            ELSE
                next_state <= SETTLE;
            END IF;
        WHEN OTHERS =>
            next_state <= WET_WAIT;
    END CASE;
END PROCESS;

set_count : PROCESS(reset_n, clk)
BEGIN
    IF(reset_n = '0') THEN
        settle_count <= (others => '0');
    ELSIF(RISING_EDGE(clk)) THEN
        IF(current_state = WET_DETECT) THEN
            settle_count <= (others => '0');
        ELSE
            settle_count <= settle_count + '1';
        END IF;
    END IF;
END PROCESS;

shift_reg : PROCESS (clk, reset_n)
BEGIN
    IF(reset_n = '0') THEN
        shift_register <= X"00";
    ELSIF(RISING_EDGE(Clk)) THEN
        IF (current_state = SEND) THEN
            IF(settle_count(3 DOWNT0 0) = LOAD_SEC) THEN
                shift_register <= INFANT_ID(11 DOWNT0 4);
            ELSIF (settle_count(3 DOWNT0 0) = LOAD_THIRD) THEN
                shift_register <= INFANT_ID(3 DOWNT0 0) &
res_sel_send & END_PATTERN;
            ELSE
                shift_register <= shift_register(6 DOWNT0 0) & '0';
            END IF;
        ELSE
            shift_register <= SYNC_PATTERN & INFANT_ID(14
DOWNT0 12);
        END IF;
    END IF;

```

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END IF;
END PROCESS;

```
resistor_sel_cnt : PROCESS(clk, reset_n)
BEGIN
    IF(reset_n = '0') THEN
        res_sel_cnt <= "00";
    ELSIF(RISING_EDGE(clk)) THEN
        IF(current_state = CH_RES) THEN
            IF(res_sel_cnt = "10") THEN
                res_sel_cnt <= "00";
            ELSE
                res_sel_cnt <= res_sel_cnt + '1';
            END IF;
        END IF;
    END IF;
END IF;
END PROCESS;
```

```
resistor_sel : PROCESS(res_sel_cnt)
BEGIN
    CASE res_sel_cnt IS
        WHEN "00" => res1 <= '1'; res2 <= 'Z';
        WHEN "01" => res1 <= 'Z'; res2 <= '1';
        WHEN "10" => res1 <= '1'; res2 <= '1';
        WHEN OTHERS => res1 <= '1'; res2 <= 'Z';
    END CASE;
END PROCESS;
```

```
sat_set : PROCESS(clk, reset_n)
BEGIN
    IF(reset_n = '0') THEN
        saturation <= '0';
    ELSIF(RISING_EDGE(clk)) THEN
        IF(current_state = WET_DETECT and res_sel_cnt = "10") THEN
            saturation <= '1';
        END IF;
    END IF;
END PROCESS;
```

```
res_sel_send <= res_sel_cnt WHEN saturation = '0' ELSE "10";
```

```
end rtl;
```

```
Wireless Mommy Unit VHDL
```

```
library IEEE;
```

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```

use IEEE.STD_LOGIC_1164.ALL;
use IEEE.STD_LOGIC_ARITH.ALL;
use IEEE.STD_LOGIC_UNSIGNED.ALL;

-- Uncomment the following lines to use the declarations that are
-- provided for instantiating Xilinx primitive components.
--library UNISIM;
--use UNISIM.VComponents.all;

entity mommy_wireless is
  Port ( por_reset_n : in std_logic;
        pb_reset_n : in std_logic;
        clk_64khz : in std_logic;
        rx_data : in std_logic;
        vibe : out std_logic;
        beep : out std_logic;
        led : out std_logic);
end mommy_wireless;

architecture mommy_wireless of mommy_wireless is

  type STATE_TYPE is (MSG_WAIT, MSG_RX, MSG_VALID, ALERT);
  signal current_state, next_state : STATE_TYPE;

  CONSTANT SYNC_PATTERN    : STD_LOGIC_VECTOR(3 DOWNTO 0) :=
    "1011";
  CONSTANT INFANT_ID       : STD_LOGIC_VECTOR(14 DOWNTO 0) :=
    X"CCC" & B"111"; -- Patient Number = 4
  CONSTANT END_PATTERN     : STD_LOGIC_VECTOR(2 DOWNTO 0) :=
    "010";

  CONSTANT MSG_LENGTH      : STD_LOGIC_VECTOR(1 DOWNTO 0)
    := "11";

  SIGNAL reset_n           : STD_LOGIC;
  SIGNAL clk               : STD_LOGIC;
  SIGNAL sample_cnt : STD_LOGIC_VECTOR(19 DOWNTO 0);
  SIGNAL sample            : STD_LOGIC_VECTOR(5 DOWNTO 0);
  SIGNAL rx_message : STD_LOGIC_VECTOR(23 DOWNTO 0);
  SIGNAL res_sel           : STD_LOGIC_VECTOR(1 DOWNTO 0);

  SIGNAL rx_data_lat : STD_LOGIC;
  SIGNAL rx_data_lat2 : STD_LOGIC;

  SIGNAL msg_sync : STD_LOGIC_VECTOR(3 DOWNTO 0);
  SIGNAL msg_id : STD_LOGIC_VECTOR(14 DOWNTO 0);

```

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```

SIGNAL msg_end   : STD_LOGIC_VECTOR(2 DOWNT0 0);

SIGNAL alert_done : STD_LOGIC;

SIGNAL vibe_int   : STD_LOGIC;
SIGNAL beep_int  : STD_LOGIC;
SIGNAL led_int    : STD_LOGIC;

begin

reset_n <= por_reset_n and pb_reset_n;
clk <= clk_64khz;

msg_sync <= rx_message(23 DOWNT0 20);
msg_id <= rx_message(19 DOWNT0 5);
res_sel <= rx_message(4 DOWNT0 3);
msg_end   <= rx_message(2 DOWNT0 0);

cur_state : PROCESS (reset_n, clk) IS
BEGIN
    IF(reset_n = '0') then
        current_state <= MSG_WAIT;
    ELSIF (RISING_EDGE(clk)) THEN
        current_state <= next_state;
    END IF;
END PROCESS cur_state;

nxt_state : PROCESS (current_state, rx_data_lat2, sample_cnt, msg_sync, msg_id,
msg_end, alert_done )
BEGIN
    CASE current_state is
        WHEN MSG_WAIT =>
            IF(rx_data_lat2 = '1') THEN --Waiting For Stop Bit
                next_state <= MSG_RX;
            ELSE
                next_state <= MSG_WAIT;
            END IF;
        WHEN MSG_RX =>
            IF(sample_cnt(10 DOWNT0 9) = MSG_LENGTH) THEN
                next_state <= MSG_VALID;
            ELSE
                next_state <= MSG_RX;
            END IF;
        WHEN MSG_VALID =>

```

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```

        IF(msg_sync = SYNC_PATTERN and msg_id = INFANT_ID and
msg_end = END_PATTERN) THEN
            next_state <= ALERT;
        ELSE
            next_state <= MSG_WAIT;
        END IF;
    WHEN ALERT =>
        IF(alert_done = '1') THEN
            next_state <= MSG_WAIT;
        ELSE
            next_state <= ALERT;
        END IF;
    WHEN OTHERS =>
        next_state <= MSG_WAIT;
END CASE;
END PROCESS;

```

-- Sync Latches

```

sync : PROCESS (clk, reset_n) IS
BEGIN

```

```

    IF(reset_n = '0') THEN

```

```

        rx_data_lat <= '0';
        rx_data_lat2 <= '0';

```

```

    ELSIF(rising_edge(Clk)) THEN

```

```

        rx_data_lat <= rx_data;
        rx_data_lat2 <= rx_data_lat;

```

```

    END IF;

```

```

END PROCESS;

```

```

smp_cnt : PROCESS(clk, reset_n) IS
BEGIN

```

```

    IF(reset_n = '0') THEN

```

```

        sample_cnt <= (others => '0');

```

```

    ELSIF(RISING_EDGE(clk)) THEN

```

```

        IF(current_state = MSG_RX or current_state = ALERT) THEN

```

```

            sample_cnt <= sample_cnt + '1';

```

```

        ELSE

```

```

            sample_cnt <= (others => '0');

```

```

        END IF;

```

```

    END IF;

```

```

END PROCESS;

```

```

rx_mesg : PROCESS(clk, reset_n) IS

```

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```

BEGIN
    IF(reset_n = '0') THEN
        rx_message <= (others => '0');
    ELSIF(RISING_EDGE(clk)) THEN
        IF(current_state = MSG_RX and sample_cnt(5 DOWNT0 0) = "111111")
THEN
            rx_message <= rx_message(22 DOWNT0 0) & sample(5);
        END IF;
    END IF;
END PROCESS;

smp_sum_cnt : PROCESS(clk, reset_n)
BEGIN
    IF(reset_n = '0') THEN
        sample <= (others => '0');
    ELSIF(RISING_EDGE(clk)) THEN
        IF(current_state = MSG_RX) THEN
            IF(sample_cnt(5 DOWNT0 0) = "111111") THEN
                sample <= "000000";
            ELSIF(rx_data_lat2 = '1') THEN
                IF(sample = "111111") THEN
                    sample <= "111111";
                ELSE
                    sample <= sample + '1';
                END IF;
            END IF;
        ELSE
            sample <= "000000";
        END IF;
    END IF;
END PROCESS;

alert_done <= sample_cnt(19);

vibe <= vibe_int;
beep <= beep_int;
led <= led_int;

mom_alrt : PROCESS(clk, reset_n) IS
BEGIN
    IF(reset_n = '0') THEN
        vibe_int <= '0';
        beep_int <= '0';
        led_int <= '0';
    ELSIF(rising_edge(clk)) THEN

```

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```

IF(current_state = ALERT) THEN
  CASE res_sel IS
    WHEN "00" => --FIRST WET
      IF(sample_cnt(16) = '1') THEN
        vibe_int <= '1';
        beep_int <= '1';
        led_int    <= '1';
      ELSE
        vibe_int <= '0';
        beep_int <= '0';
        led_int <= '0';
      END IF;
    WHEN "01" => --SECOND WET
      IF(sample_cnt(17) = '1') THEN
        vibe_int <= '1';
        beep_int <= '1';
        led_int    <= '1';
      ELSE
        vibe_int <= '0';
        beep_int <= '0';
        led_int <= '0';
      END IF;
    WHEN "10" => --SATURATION
      IF(sample_cnt(18) = '1') THEN
        vibe_int <= '1';
        beep_int <= '1';
        led_int    <= '1';
      ELSE
        vibe_int <= '0';
        beep_int <= '0';
        led_int <= '0';
      END IF;
    WHEN OTHERS =>
      vibe_int <= '0';
      beep_int <= '0';
      led_int <= '0';
  END CASE;
ELSE
  vibe_int <= '0';
  beep_int <= '0';
  led_int <= '0';
END IF;
END IF;
END PROCESS;

END mommy_wireless;

```

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Patient Module:

--Patient Module
 --Property of Frequency Corp.

library IEEE;
 use IEEE.STD_LOGIC_1164.ALL;
 use IEEE.STD_LOGIC_ARITH.ALL;
 use IEEE.STD_LOGIC_UNSIGNED.ALL;

-- Uncomment the following lines to use the declarations that are
 -- provided for instantiating Xilinx primitive components.
 --library UNISIM;
 --use UNISIM.VComponents.all;

entity Patient_Top is

Port (
 --Chip CNTL Signals
 Chip_RESET : in std_logic;
 CLK : in std_logic;
 --Monitor input signals
 Nine11_IN : in std_logic;
 Call_IN : in std_logic;
 Visit_IN : in std_logic;
 Fall_IN : in std_logic;
 Motion_IN : in std_logic;
 Location_IN : in std_logic;
 Wet_IN : in std_logic;
 Wet_Reset : in std_logic;
 --Transmit Signals
 Transmit_EN : out std_logic;
 Data_OUT : out std_logic
);

end Patient_Top;

architecture RTL of Patient_Top is

type STATE_TYPE is (S0, S1, S2, S3, S4);
 signal current_state, next_state : STATE_TYPE;

-- Monitor Signal Latch
 signal Nine11_IN_lat : std_logic;
 signal Call_IN_lat : std_logic;
 signal Visit_IN_lat : std_logic;

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```

signal Fall_IN_lat : std_logic;
signal Motion_IN_lat : std_logic;
signal Location_IN_lat : std_logic;
signal Wet_IN_lat : std_logic;
signal Wet_Reset_lat : std_logic;

```

-- Debounce Signal Pulse and Latches

```

signal Nine11_IN_Q1 : std_logic;
signal Call_IN_Q1 : std_logic;
signal Visit_IN_Q1 : std_logic;
signal Fall_IN_Q1 : std_logic;
signal Motion_IN_Q1 : std_logic;
signal Location_IN_Q1 : std_logic;
signal Wet_IN_Q1 : std_logic;
signal Wet_Reset_Q1 : std_logic;

```

```

signal Nine11_IN_Q2 : std_logic;
signal Call_IN_Q2 : std_logic;
signal Visit_IN_Q2 : std_logic;
signal Fall_IN_Q2 : std_logic;
signal Motion_IN_Q2 : std_logic;
signal Location_IN_Q2 : std_logic;
signal Wet_IN_Q2 : std_logic;
signal Wet_Reset_Q2 : std_logic;

```

```

signal Nine11_IN_Q3 : std_logic;
signal Call_IN_Q3 : std_logic;
signal Visit_IN_Q3 : std_logic;
signal Fall_IN_Q3 : std_logic;
signal Motion_IN_Q3 : std_logic;
signal Location_IN_Q3 : std_logic;
signal Wet_IN_Q3 : std_logic;
signal Wet_Reset_Q3 : std_logic;

```

```

signal Nine11_IN_debounce : std_logic;
signal Call_IN_debounce : std_logic;
signal Visit_IN_debounce : std_logic;
signal Fall_IN_debounce : std_logic;
signal Motion_IN_debounce : std_logic;
signal Location_IN_debounce : std_logic;
signal Wet_IN_debounce : std_logic;
signal Wet_Reset_debounce : std_logic;

```

--Monitor Signal Flags

```

signal Wet_IN_FLAG : std_logic;

```


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```

-- Transmit Enable internal Signal
signal Transmit_EN_int : std_logic;

signal shift_register : std_logic_vector(51 downto 0);
signal shift_count : natural range 0 to 52;

constant Sync_Fill : std_logic_vector(3 downto 0) := "0000";
constant Sync_Pattern : std_logic_vector(3 downto 0) := "1011";
constant System_ID : std_logic_vector(2 downto 0) := "100";
constant Patient_ID : std_logic_vector(8 downto 0) := "100000000";
constant Pendant_ID : std_logic_vector(4 downto 0) := "10000";
constant Fill_Pattern : std_logic_vector(15 downto 0) := X"0000";
constant End_Pattern : std_logic_vector(2 downto 0) := "010";

begin

-- OUTPUT Concurrent Signals
-- Transmit enable
Transmit_EN <= '0' when Chip_Reset = '0' else Transmit_EN_int when rising_edge(Clk);
-- Shift Data OUT
Data_OUT <= shift_register(51);

-- Debounce incoming signals
Nine11_IN_debounce <= Nine11_IN_Q1 and Nine11_IN_Q2 and (not Nine11_IN_Q3);
Call_IN_debounce <= Call_IN_Q1 and Call_IN_Q2 and (not Call_IN_Q3);
Visit_IN_debounce <= Visit_IN_Q1 and Visit_IN_Q2 and (not Visit_IN_Q3);
Fall_IN_debounce <= Fall_IN_Q1 and Fall_IN_Q2 and (not Fall_IN_Q3);
Motion_IN_debounce <= Motion_IN_Q1 and Motion_IN_Q2 and (not Motion_IN_Q3);
Location_IN_debounce <= Location_IN_Q1 and Location_IN_Q2 and (not
Location_IN_Q3);
Wet_IN_debounce <= Wet_IN_Q1 and Wet_IN_Q2 and (not Wet_IN_Q3);
Wet_Reset_debounce <= Wet_Reset_Q1 and Wet_Reset_Q2 and (not Wet_Reset_Q3);

-- DeBounce Latches
dbounce : process (Clk, Chip_Reset) IS
begin
    if(Chip_Reset = '0') then
        Nine11_IN_Q1 <= '0';
        Call_IN_Q1 <= '0';
        Visit_IN_Q1 <= '0';
        Fall_IN_Q1 <= '0';
        Motion_IN_Q1 <= '0';
        Location_IN_Q1 <= '0';

```

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```
Wet_IN_Q1 <= '0';
Wet_Reset_Q1 <= '0';
```

```
Nine11_IN_Q2 <= '0';
Call_IN_Q2 <= '0';
Visit_IN_Q2 <= '0';
Fall_IN_Q2 <= '0';
Motion_IN_Q2 <= '0';
Location_IN_Q2 <= '0';
Wet_IN_Q2 <= '0';
Wet_Reset_Q2 <= '0';
```

```
Nine11_IN_Q3 <= '0';
Call_IN_Q3 <= '0';
Visit_IN_Q3 <= '0';
Fall_IN_Q3 <= '0';
Motion_IN_Q3 <= '0';
Location_IN_Q3 <= '0';
Wet_IN_Q3 <= '0';
Wet_Reset_Q3 <= '0';
```

```
elsif(rising_edge(Clk)) then
```

```
Nine11_IN_Q1 <= Nine11_IN;
Call_IN_Q1 <= Call_IN;
Visit_IN_Q1 <= Visit_IN;
Fall_IN_Q1 <= Fall_IN;
Motion_IN_Q1 <= Motion_IN;
Location_IN_Q1 <= Location_IN;
Wet_IN_Q1 <= Wet_IN;
Wet_Reset_Q1 <= Wet_Reset;
```

```
Nine11_IN_Q2 <= Nine11_IN_Q1;
Call_IN_Q2 <= Call_IN_Q1;
Visit_IN_Q2 <= Visit_IN_Q1;
Fall_IN_Q2 <= Fall_IN_Q1;
Motion_IN_Q2 <= Motion_IN_Q1;
Location_IN_Q2 <= Location_IN_Q1;
Wet_IN_Q2 <= Wet_IN_Q1;
Wet_Reset_Q2 <= Wet_Reset_Q1;
```

```
Nine11_IN_Q3 <= Nine11_IN_Q2;
Call_IN_Q3 <= Call_IN_Q2;
Visit_IN_Q3 <= Visit_IN_Q2;
Fall_IN_Q3 <= Fall_IN_Q2;
Motion_IN_Q3 <= Motion_IN_Q2;
```

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```

        Location_IN_Q3 <= Location_IN_Q2;
        Wet_IN_Q3 <= Wet_IN_Q2;
        Wet_Reset_Q3 <= Wet_Reset_Q2;

    end if;

end process dbounce;

-- Latch Monitor signals into the chip.
sig_Latch : process (Clk, Chip_Reset, current_state) IS
begin
    if(Chip_Reset = '0') then
        Nine11_IN_lat <= '0';
        Call_IN_lat <= '0';
        Visit_IN_lat <= '0';
        Fall_IN_lat <= '0';
        Visit_IN_lat <= '0';
        Motion_IN_lat <= '0';
        Location_IN_lat <= '0';
        Wet_RESET_lat <= '0';

    elsif(rising_edge(Clk)) then
        if(current_state = S4) then
            Nine11_IN_lat <= '0';
        elsif(Nine11_IN_debounce = '1' and Nine11_IN_lat = '0') then
            Nine11_IN_lat <= '1';
        end if;

        if(current_state = S4) then
            Call_IN_lat <= '0';
        elsif(Call_IN_debounce = '1' and Call_IN_lat = '0') then
            Call_IN_lat <= '1';
        end if;

        if(current_state = S4) then
            Visit_IN_lat <= '0';
        elsif(Visit_IN_debounce = '1' and Visit_IN_lat = '0') then
            Visit_IN_lat <= '1';
        end if;

        if(current_state = S4) then
            Fall_IN_lat <= '0';
        elsif(Fall_IN_debounce = '1' and Fall_IN_lat = '0') then
            Fall_IN_lat <= '1';
        end if;
    end if;
end process;

```

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```

        if(current_state = S4) then
            Visit_IN_lat <= '0';
        elsif(Visit_IN_debounce = '1' and Visit_IN_lat = '0') then
            Visit_IN_lat <= '1';
        end if;

        if(current_state = S4) then
            Motion_IN_lat <= '0';
        elsif(Motion_IN_debounce = '1' and Motion_IN_lat = '0') then
            Motion_IN_lat <= '1';
        end if;

        if(current_state = S4) then
            Location_IN_lat <= '0';
        elsif(Location_IN_debounce = '1' and Location_IN_lat = '0') then
            Location_IN_lat <= '1';
        end if;

        if(current_state = S4) then
            Wet_RESET_lat <= '0';
        elsif(Wet_RESET_debounce = '1' and Wet_RESET_lat = '0') then
            Wet_RESET_lat <= '1';
        end if;
    end if;
end process sig_Latch;

wet_lat : process (Clk, Chip_RESET, Wet_RESET_lat) IS
begin
    if(Chip_RESET = '0') then
        Wet_IN_lat <= '0';
    elsif(rising_edge(Clk)) then
        if(Wet_RESET_lat = '1') then
            Wet_IN_lat <= '0';
        elsif(Wet_IN_debounce = '1' and Wet_IN_lat = '0') then
            Wet_IN_lat <= '1';
        end if;
    end if;
end process wet_lat;

cur_state : process (Chip_Reset, Clk) IS
begin
    if(Chip_Reset = '0') then
        current_state <= S0;
    elsif (rising_edge(Clk)) then

```

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```

        current_state <= next_state;
    end if;
end process cur_state;

comb_logic : process (current_state, Nine11_IN_lat, Call_IN_lat, Visit_IN_lat,
Fall_IN_lat, Motion_IN_lat, Location_IN_lat, Wet_Reset_lat, Wet_IN_FLAG,
Wet_IN_lat, shift_count) IS
begin
    case current_state is
        when S0 =>
            -- outputs
            Transmit_EN_int <= '0';

            --next state
            if(Nine11_IN_lat = '1' or Call_IN_lat = '1' or
Visit_IN_lat = '1' or Fall_IN_lat = '1' or
Motion_IN_lat = '1' or Location_IN_lat = '1' or
Wet_Reset_lat = '1') then

                next_state <= S1;

            elsif (Wet_IN_FLAG = '0' and Wet_IN_lat = '1') then
                next_state <= S1;
            else
                next_state <= S0;
            end if;
        when S1 =>
            Transmit_EN_int <= '1';
            next_state <= S2;
        when S2 =>
            Transmit_EN_int <= '1';
            next_state <= S3;
        when S3 =>
            Transmit_EN_int <= '1';
            next_state <= S2;
            if(shift_count < 51) then
                next_state <= S3;
            else
                next_state <= S4;
            end if;
        when S4 =>
            Transmit_EN_int <= '0';
            next_state <= S0;
        when others =>
            Transmit_EN_int <= '0';
            next_state <= S0;
    end case;
end process;

```

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```

    end case;
end process comb_logic;

```

```

shift_reg : process (current_state, Clk, Chip_RESET) IS
begin
    if(Chip_RESET = '0') then
        shift_register <= Sync_Fill &
            Sync_Pattern &
            System_ID &
            Patient_ID &
            Pendant_ID &
            X"00" &
            Fill_Pattern &
            End_Pattern;
    elsif(rising_edge(Clk)) then
        if (current_state = S1) then
            shift_register <= Sync_Fill & Sync_Pattern & System_ID &
                Patient_ID & Pendant_ID &
                Nine11_IN_lat & Call_IN_lat & Visit_IN_lat &
                Fall_IN_lat & Motion_IN_lat &
                Location_IN_lat & Wet_IN_lat & Wet_Reset_lat &
                Fill_Pattern & End_Pattern;
        elsif (current_state = S3) then
            shift_register <= shift_register(50 downto 0) & '0';
        end if;
    end if;
end process shift_reg;

```

```

shift_cnt : process ( current_state; Clk, Chip_RESET) IS
begin
    if(Chip_RESET = '0') then
        shift_count <= 0;
    elsif( rising_edge(Clk)) then
        if( current_state = S0) then
            shift_count <= 0;
        elsif(current_state = S3) then
            shift_count <= shift_count + 1;
        end if;
    end if;
end process shift_cnt;

```

```

Wet_IN_FL : process (Clk, Chip_RESET, Wet_RESET_lat) IS
begin
    if(Chip_RESET = '0' or Wet_RESET_lat = '1') then

```

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```
Wet_IN_FLAG <= '0';
elsif(rising_edge(Clk)) then
  if (current_state = S1 and Wet_IN_lat = '1') then
    Wet_IN_FLAG <= '1';
  end if;
end if;
end process Wet_IN_FL;

end RTL;
```

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Claims

What is claimed is:

1. A patient monitoring system for detecting wetness in an article, comprising:
 - a. a sensor means configured with a diaper, wherein said sensor means is adapted to detect a wetness event occurring within said diaper;
 - b. a monitoring unit comprising a monitoring system controller means in communication with said sensor means, wherein said monitoring system controller means monitors said sensor means and generates data associated with detected wetness events relative to said diaper so that said monitoring system controller means can detect a variety of wetness conditions and discern between valid wetness events and false or erroneous wetness events, said diaper providing attaching means for removably attaching said monitoring unit to said diaper;
 - c. a notification means for informing of the said data associated with detected wetness events relative to said diaper, and the notification means being activated by the output of the monitoring system controller means.
2. The patient monitoring system according to claim 1, wherein said notification means further comprises a display means configured with said monitoring unit and in communication with said monitoring system controller, wherein said display means is adapted to display said data associated with said detected wetness event and corresponding condition of said diaper;
3. The patient monitoring system according to claim 1, wherein said notification means further comprises a sound generating means configured with said monitoring unit and in communication with said monitoring system controller, wherein said sound generating means is responsive to the detection of a wetness event;
4. The patient monitoring system according to claim 1, said system further comprising: a data port configured with said monitoring unit and in

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communication with said monitoring system controller, wherein said data port facilitates communications between said monitoring unit and an external system, wherein said communications include said data associated with said detected wetness event and corresponding condition of said diaper.

5. The patient monitoring system according to claim 1, wherein said notification means further comprises:
 - a. an external display means, configured with said monitoring unit and in communication with said monitoring system controller, wherein said display means is adapted to display said data associated with said detected wetness event and corresponding condition of said diaper;
 - b. a wireless transmitter configured with said monitoring unit and in communication with said monitoring system controller, wherein said wireless transmitter facilitates communications between said monitoring unit and said external display means.
6. The patient monitoring system according to claim 5, wherein said external display means in communication with said wireless transmitter is capable of receiving communications from a plurality of said monitoring units.
7. The patient monitoring system according to claim 5, further comprising:
 - a. a recording means configured to record a plurality of events associated with a caregiver visit to the wearer of said diaper, wherein each recorded event represents at least one of the following: an observation of the condition of the wearer of said diaper, a service provided to the wearer of the diaper, the name and identifying information of the caregiver, and the name and identifying information of the wearer of the diaper;
 - b. a caregiver unit comprising a caregiver system controller means in communication with said recording means, wherein said caregiver system controller means is operatively associated with said recording means and generates data associated with recorded events relative to a caregiver visit;
8. The patient monitoring system according to claim 7, further comprising a data port configured with said caregiver unit and in communication with said caregiver system controller, wherein said data port facilitates communications between said caregiver unit and an external system, wherein said communications include

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said generated data associated with said recorded events relative to a caregiver visit.

9. The patient monitoring system according to claim 7, further comprising a wireless transmitter configured with said caregiver unit and in communication with said caregiver system controller, wherein said wireless transmitter facilitates communications between said caregiver unit and said external display unit, wherein said communications includes said generated data associated with said recorded events relative to a caregiver visit.
10. The patient monitoring system according to claim 1, wherein said notification means further comprises:
 - a. an external sound generating means configured with said monitoring unit and in communication with said monitoring system controller, wherein said sound generating means is responsive to the detection of a wetness event; or
 - b. a wireless transmitter configured with said monitoring unit and in communication with said monitoring system controller, wherein said wireless transmitter facilitates communications between said monitoring unit and said external sound generating means.
11. The patient monitoring system according to claim 1, wherein said external sound generations means in communication with said wireless transmitter is capable of receiving communications from a plurality of said monitoring units.
12. The patient monitoring system according to claim 1, wherein said monitoring system controller of said monitoring unit further comprises a means for detecting a plurality of levels of wetness of the said diaper in real-time.
13. The patient monitoring system according to claim 1, wherein said monitoring system controller of said monitoring unit further comprises a means for determining the rate of change of the level of wetness of the diaper in real-time.
14. The patient monitoring system according to claim 1, wherein said monitoring system controller of said monitoring unit further comprises a means for automatically adjusting the sensitivity of said sensor means.
15. The patient monitoring system according to claim 1, wherein said sensor means includes at least one sensor selected from the group comprising:

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- a. a motion sensor for detecting movement within said diaper;
 - b. a fall sensor for detecting when the wearer of said diaper falls;
 - c. a location sensor for detecting the location of the wearer of said diaper;
 - d. a caregiver visit sensor for detecting when a caregiver visits the wearer of said diaper;
 - e. a call sensor to enable the wearer of said diaper to alert the caregiver that they need assistance;
 - f. a low battery sensor to detect when the battery of said monitoring unit has low voltage.
16. The patient monitoring system according to claim 1 wherein said sensor means comprises:
- a. a laminated metal film, having a front side and a back side, said laminated metal film extending approximately the entire length and approximately the entire width of the diaper;
 - b. a mylar material attached to said back side of said laminated metal film thereby providing tensile strength and permeability to the said laminated metal film;
 - c. where said front side of said laminated metal film is adhesively secured to the diaper.
17. The patient monitoring system according to claim 1 wherein said sensor means are composed of metallized thread.
18. A method of sensing and monitoring wetness in an article, said method comprising the steps of:
- a. configuring of a sensor in a diaper which can detect wetness;
 - b. removably attaching a monitoring unit to said diaper, the monitoring unit comprising a monitoring system controller in communication with said sensor, wherein said monitoring system controller monitors said sensor

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and generates data associated with detected wetness events relative to said diaper so that said monitoring system controller can detect a variety of wetness conditions and discern between valid wetness events and false or erroneous wetness events;

- c. sensing a plurality of wetness events in said diaper responsive to said sensor;
 - d. activating a notification of the said data associated with detected wetness events relative to said diaper.
19. The method as claimed in claim 14, wherein the sensing step further includes detecting a plurality of levels of wetness of the said diaper in real-time.
 20. The method as claimed in claim 14, wherein the sensing step further includes determining the rate of change of the level of wetness of the diaper in real-time.
 21. The method as claimed in claim 14, wherein the sensing step further includes automatically adjusting the sensitivity of said sensor means.
 22. The method as claimed in claim 14, wherein the sensing step further includes detecting the location of the said diaper.
 23. The method as claimed in claim 14, wherein the sensing step further includes detecting when the wearer of said diaper moves.
 24. The method as claimed in claim 14, wherein the sensing step further includes detecting when the wearer of said diaper falls.
 25. The method as claimed in claim 14, wherein the sensing step further includes detecting when a caregiver visits the wearer of the diaper.
 26. The method as claimed in claim 14, wherein the sensing step further includes detecting when the wearer of the diaper request the assistance of a caregiver.
 27. The method as claimed in claim 14, wherein the sensing step further includes detecting when said monitoring unit requires a new battery.
 28. The method as claimed in claim 14, wherein the activating a notification step further includes displaying said data.

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29. The method as claimed in claim 14, wherein the activating a notification step further includes generating a sound.
30. The method as claimed in claim 14, wherein the activating a notification step further includes wirelessly transmitting said data for display on an external display.
31. The method as claimed in claim 14, wherein the activating a notification step further includes generating a sound on an external sound generator.
32. The method as claimed in claim 14, wherein the activating a notification step further includes communicating said data to an external system.
33. The method as claimed in claim 14, wherein said method further comprises the step of recording an event associated with a caregiver visit to the wearer of said diaper, wherein each recorded event represents at least one of the following: an observation of the condition of the wearer of said diaper, a service provided to the wearer of the diaper, the name and identifying information of the caregiver, and the name and identifying information of the wearer of the diaper;
34. The method as claimed in claim 29, wherein said method further comprises the step of communicating said recorded event to an external system.
35. The method as claimed in claim 29, wherein said method further comprises the step of wirelessly transmitting said recorded event to an external system.
36. The method as claimed in claim 14, wherein the sensing step further comprises at least one of the steps of:
 - a. detecting a plurality of levels of wetness of the said diaper in real-time;
 - b. determining the rate of change of the level of wetness of the diaper in real-time;
 - c. automatically adjusting the sensitivity of said sensor means;
 - d. detecting when the wearer of said diaper moves.
 - e. detecting when the wearer of said diaper falls.
 - f. detecting when a caregiver visits the wearer of the diaper.

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- g. detecting when the wearer of the diaper requests the assistance of a caregiver.
- h. detecting when said monitoring unit requires a new battery.

37. A diaper produced according to the method of claim 32.

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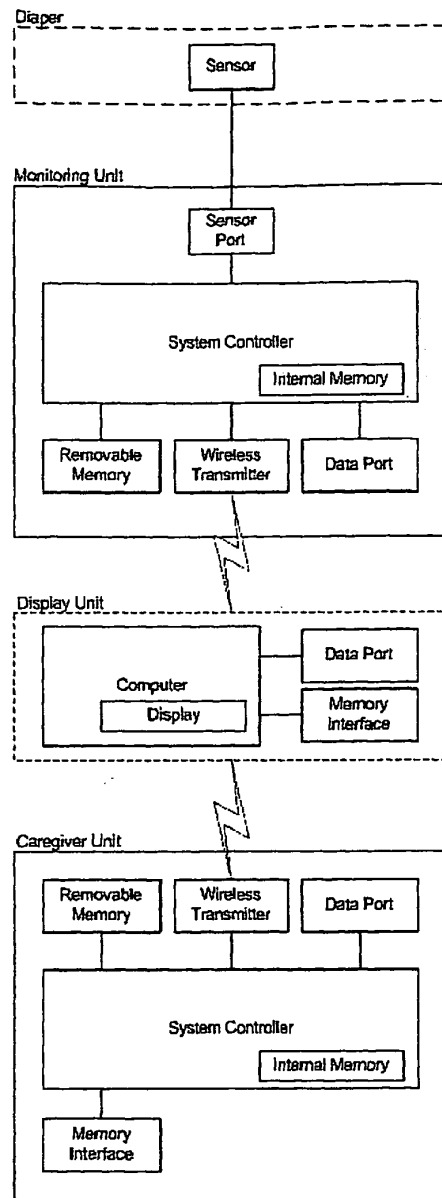


FIG. 1

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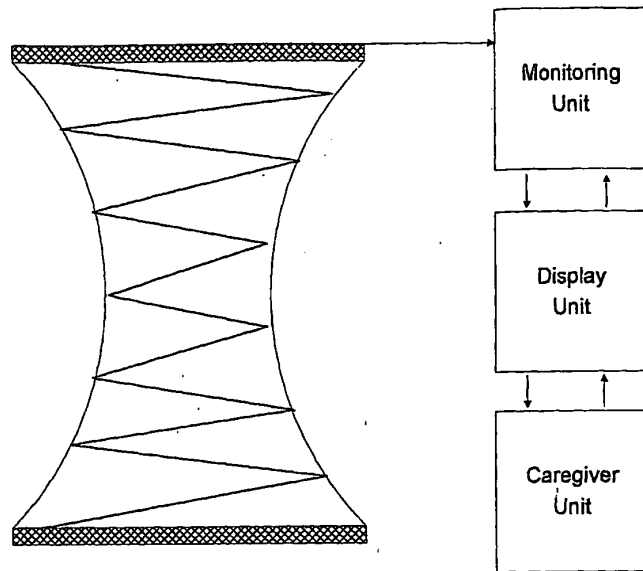


FIG. 2

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Caregiver Unit

Patient John Doe 1234567

100 10 1

<input type="checkbox"/> Transfer	<input type="checkbox"/> Bedsores
<input type="checkbox"/> Bathed	<input type="checkbox"/> Bleeding
<input type="checkbox"/> Cleaned	<input type="checkbox"/> Change in Activity
<input type="checkbox"/> Bed Made	<input type="checkbox"/> Chest Pain
<input type="checkbox"/> Dressing or Hygiene	<input type="checkbox"/> Cold Symptoms
<input type="checkbox"/> Footcare	<input type="checkbox"/> Dehydration
<input type="checkbox"/> Incontinence Care	<input type="checkbox"/> Depressed / Confused
<input type="checkbox"/> Linens Changed	<input type="checkbox"/> Dizziness
<input type="checkbox"/> Oral Care	<input type="checkbox"/> Fall
<input type="checkbox"/> Showered	<input type="checkbox"/> Hazard Exists
<input type="checkbox"/> Therapy	<input type="checkbox"/> Loss of Appetite
<input type="checkbox"/> Toileting	<input type="checkbox"/> Nausea or Vomiting

Sign-In

Send

0 1 2 3 4 5 6 7 8 9

FIG. 3

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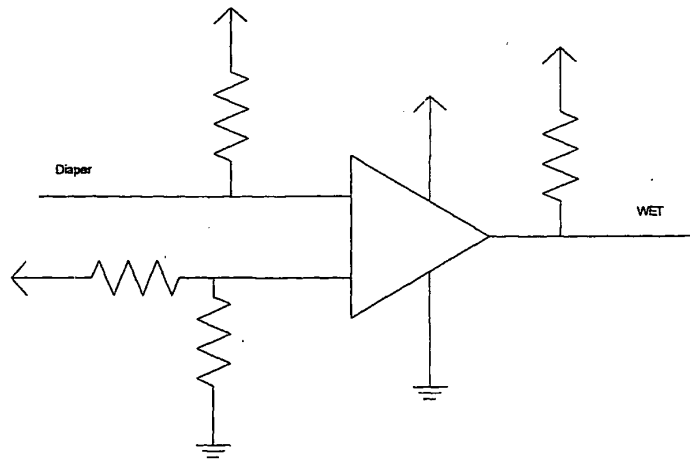


FIG. 4

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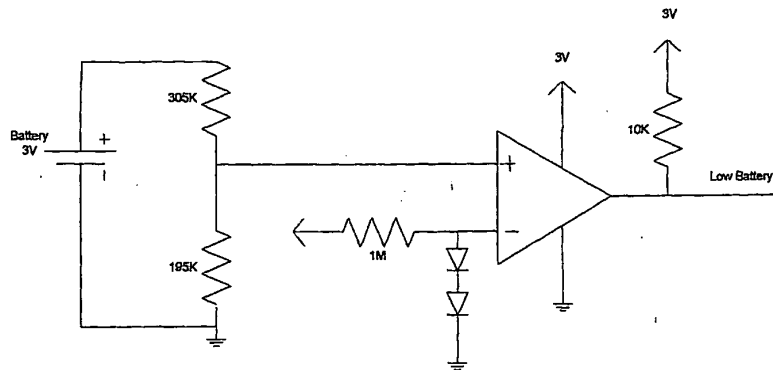


FIG. 5

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DIAPER WET WIRING

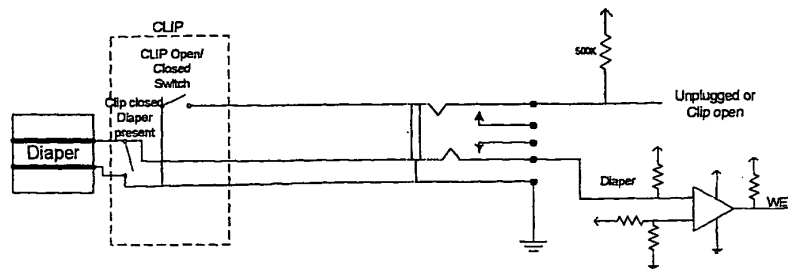
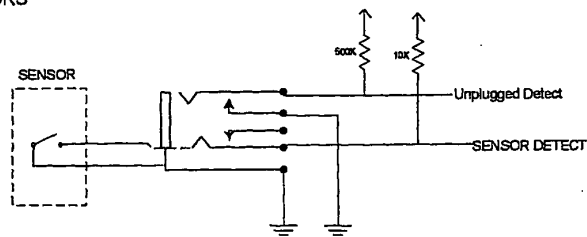
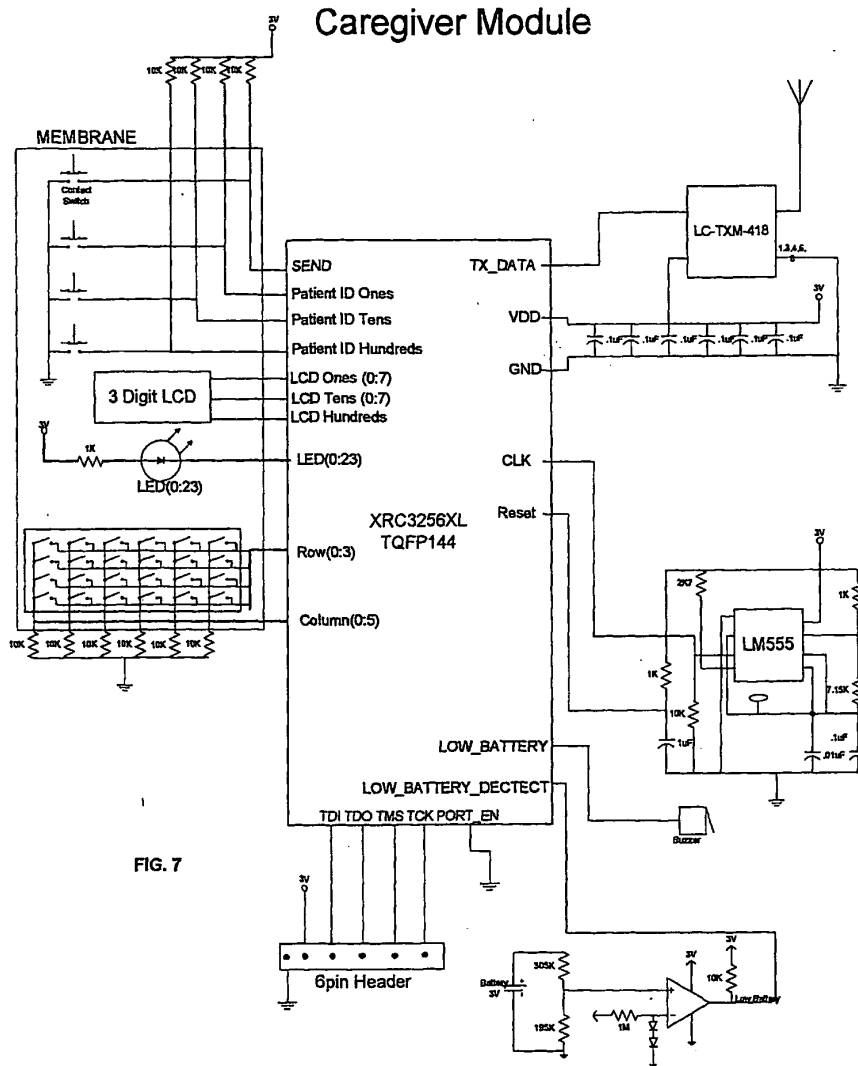
ALL OTHER SENSORS
WIRING

FIG. 6

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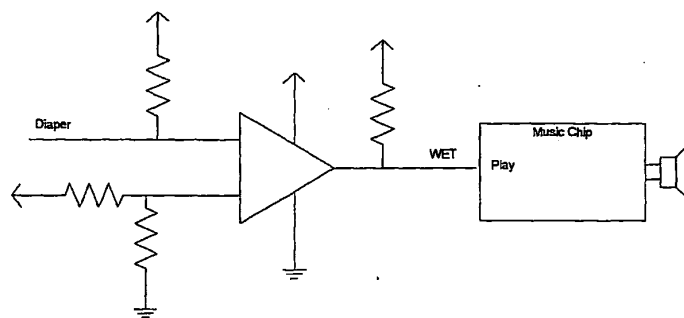


FIG. 8

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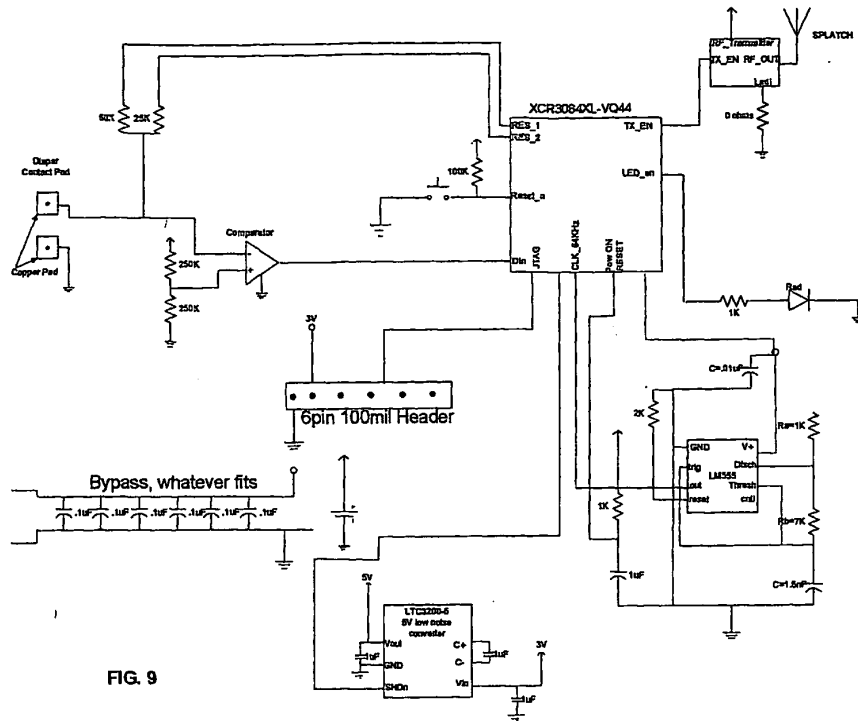


FIG. 9

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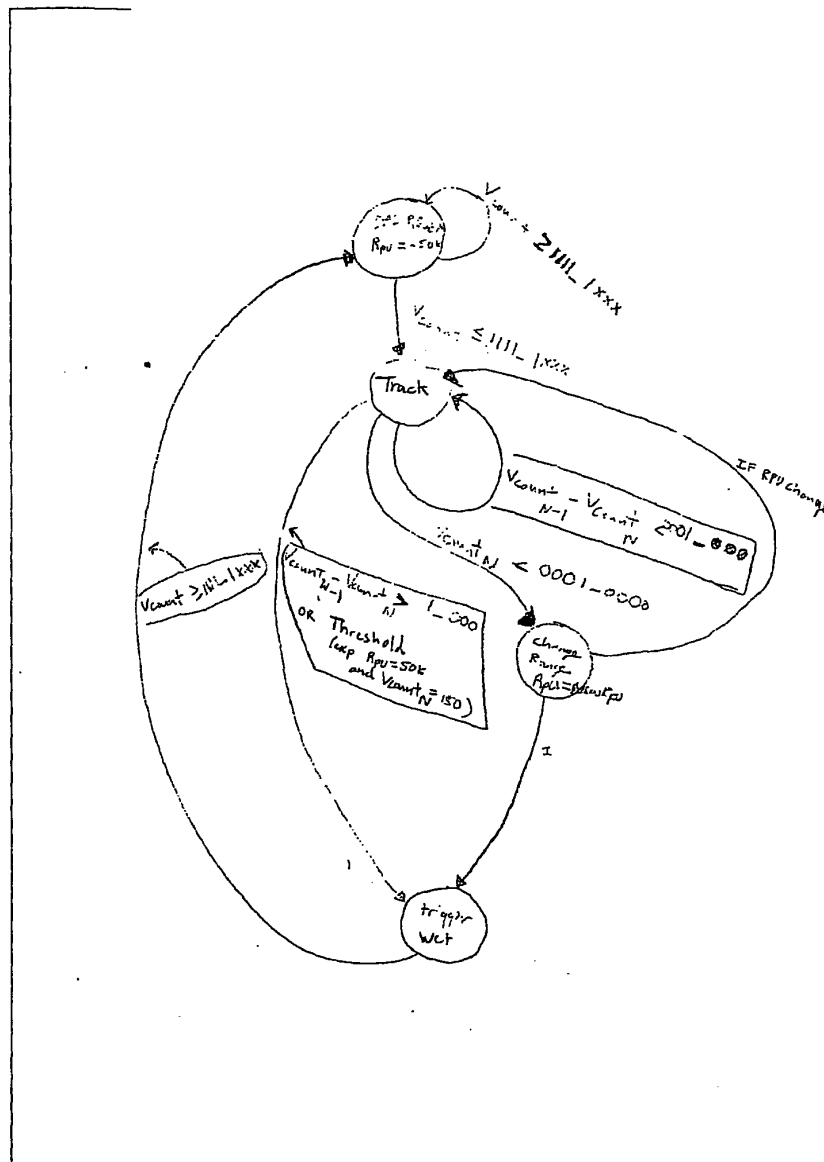


FIG. 10



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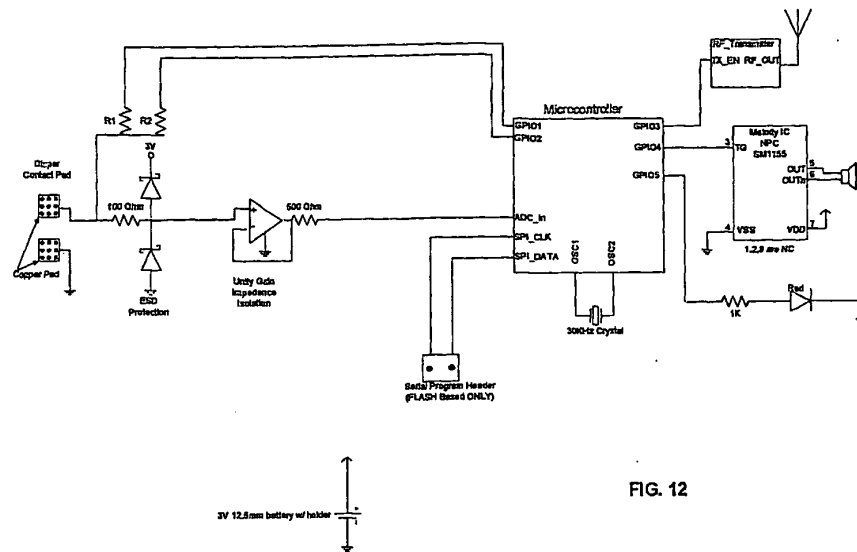
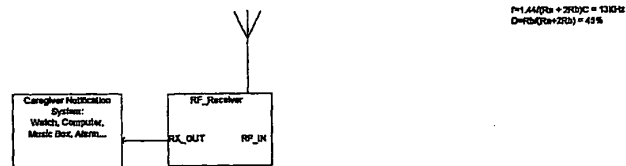


FIG. 12


$$D = R_D / (R_D + 2R_B) = 45\%$$



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Patient Module

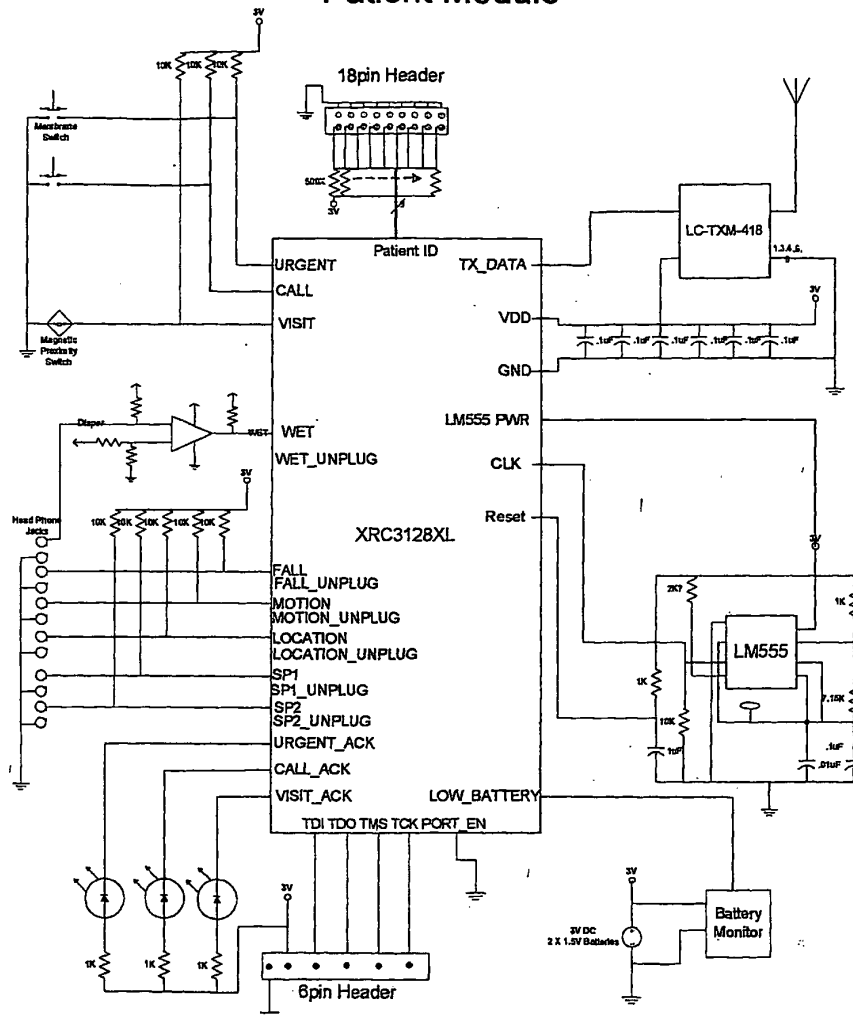


FIG. 14

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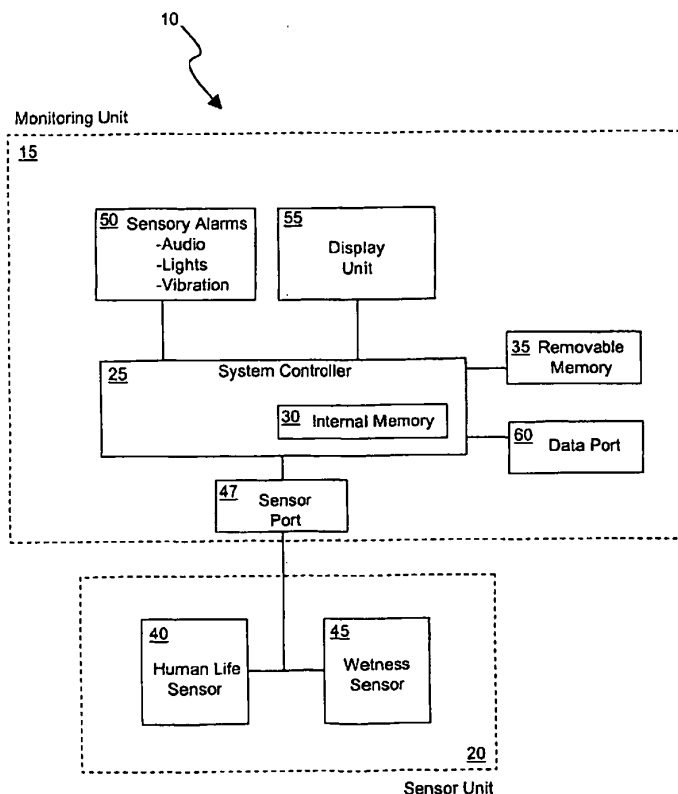
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(54) Title: WETNESS MONITORING SYSTEM



(57) Abstract: A personal care monitoring system (10) is disclosed. In accordance with one embodiment, the monitoring system may include a wetness sensor (45) configured to detect a wetness event occurring within an associated diaper (80), and a human life sensor (40) configured to detect presence of human life relative to the associated diaper. A monitoring unit (15) having a system controller (25) in communication with the wetness and human life sensors may be utilized in such a manner that the system controller monitors the wetness and human life sensors and generates data associated with detected wetness events and presence of human life relative to the associated diaper.

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WETNESS MONITORING SYSTEM

TECHNICAL FIELD

The present invention relates generally to a wetness monitoring system, and in particular, to a wetness monitoring system that permits qualitative assessment of provided care.

BACKGROUND ART

An assortment of wetness detecting systems and associated devices have been previously proposed and implemented to monitor the condition of a diaper, bedding, adult incontinence brief, and other similar articles. The general principle of many wetness detection systems is to implement some sort of urine or wetness detector in cooperation with a display or alarm device. Some systems activate an audible or visible alarm to indicate the presence of urine within the diaper. This is typically accomplished by the detection of some threshold wetness level within a diaper.

Concerned parents have increasingly desired to know whether or not their infant or infirm adult has been subjected to excessive time in a wet diaper, for example, because of a dilatory caregiver. This information is often helpful to permit a parent or guardian, for example, to qualitatively assess care provided by a caregiver to an infant or infirm adult. In an apparent response to these needs, some systems purport to track and record the timing and frequency of urinating events and associated diaper changes.

A common problem encountered by many existing wetness detector systems is a susceptibility to system tampering and data manipulation by a less than scrupulous caregiver. For example, some systems may be easily disconnected from the infant's diaper and simply tossed aside by a caregiver in anticipation of improper or negligent care.

While there have been some attempts at implementing wetness monitoring

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systems that permit qualitative assessment of care provided by a caregiver, for example, these attempts have met with varying levels of success and improvement is still needed.

DISCLOSURE OF INVENTION

5 A personal care monitoring system according to one embodiment includes a wetness sensor configured to detect a wetness event occurring within an associated diaper, and a human life sensor configured to detect presence of human life relative to the diaper. A monitoring unit having a system controller in communication with the wetness and human life sensors may be utilized in such a manner that the system controller monitors the wetness and human life sensors and generates data associated with detected wetness events and detected presence of human life relative to the diaper.

10

 These and other aspects, features and advantages of the present invention will become more apparent upon consideration of the following description of preferred embodiments taken in conjunction with the accompanying drawings, in which like reference numerals designate like parts throughout.

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BRIEF DESCRIPTION OF DRAWINGS

FIG. 1A is a block diagram showing one embodiment of the present invention;

FIG. 1B is a block diagram showing an alternative embodiment of the present invention;

5 FIG. 1C is a block diagram showing another alternative embodiment of the present invention;

FIG. 2 is a flowchart showing exemplary operations for implementing a personal care monitoring system according to some embodiments of the present invention;

10 FIGS. 3A and 3B are block diagrams showing some of the many configurations possible for implementing the present invention;

FIGS. 4A and 4B are more detailed views of possible sensor implementations according to some embodiments of the present invention;

FIG. 5 is a diagram of a monitoring system having several integrated features in accordance with some embodiments of the present invention;

15 FIG. 6 is a diagram showing one of the many configurations possible for implementing a display unit in accordance with the present invention;

FIG. 7 is an example of the types of data that may be acquired and provided in accordance with the invention;

20 FIG. 8 is an exploded perspective view of an exemplary monitoring unit in accordance with some embodiments of the invention;

FIGS. 9A and 9B are perspective views showing, respectively, partially assembled and assembled views of the exemplary monitoring unit of FIG. 8; and

FIGS. 10A through 10C are top, front, and side views, respectively, of an assembled monitoring unit of FIG. 8.

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BEST MODE FOR CARRYING OUT THE INVENTION

In the following description of preferred embodiments, reference is made to the accompanying drawings, which form a part hereof, and which show by way of illustration, specific embodiments of the invention. It is to be understood by those of working skill in
5 this technological field that other embodiments may be utilized, and structural, electrical, as well as procedural changes may be made without departing from the scope of the present invention.

The terms "wetness" and "wetness event" are to be understood as including human urination, defecation, and other bodily discharge events. Furthermore, the term "diaper"
10 as used herein refers to disposable and reusable devices which absorb and contain a wetness event and may include diapers, pants-type diapers, training pants, and adult incontinence briefs which are widely used in the care of infants, toddlers, and incontinent adults.

It is to be understood that a personal care monitoring system and associated
15 methods of the present invention are applicable to a wide variety of situations where the qualitative monitoring of provided care is desired. Although several implementations will be discussed in the context of the invention configured with an infant diaper, it will be appreciated that slight modifications of the system may make it even more applicable to other systems and care giving situations without the need of inventive faculty.

20 Referring now to FIG. 1, a block diagram of one embodiment of the present invention is shown and generally designated 10. As shown, monitoring system 10 generally includes a monitoring unit 15 and a sensor unit 20. Control of some or all of the monitoring and sensor units 15, 20 may be provided by an appropriate processing device, such as system controller 25.

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System controller 25 may include a microprocessor, microcontroller, application specific integrated circuit (ASIC), embedded processor, or any other suitable control or processing device. Controller 25 is typically configured with appropriate memory for processing, recording, and storing data relating to personal care monitoring of an individual. For example, controller 25 may be configured with internal memory 30 or removable memory 35, or both. Internal and removable memory 30, 35 may be any type or combination of any suitable volatile or non-volatile memory device such as random access memory (RAM), electrically erasable programmable read-only memory (EEPROM), erasable programmable read-only memory (EPROM), programmable read-only memory (PROM), read-only memory (ROM), magnetic memory, flash memory, or other similar memories. Data obtained in accordance with the invention will be collectively referred to as personal care data, and may be stored using any of the just-described memory devices using any suitable technique.

The monitoring unit 15 is shown in communication with the sensor unit 20 which typically comprises a human life sensor 40 and a wetness sensor 45. A sensor port 47 may be used to facilitate an electronic coupling between the monitoring and sensor units 15, 20. Typically, the sensor port 47 provides a detachable coupling between components, but hard-wired configurations are possible if so desired. According to some embodiments, the invention may be implemented by positioning sensor unit 20 within a diaper (not shown in this Figure), while the monitoring unit 15 is attached to the outside of the diaper; however, many other configurations are possible and will be described in more detail herein.

Life sensor 40 may include any suitable device which can detect human presence and/or absence. For example, life sensor 40 may be configured as a heat sensor, salinity sensor, heart rate monitor, conductance device, pH measuring device, and the like.

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Regardless of the type of sensor implemented, instances of human presence and/or absence relative to an associated diaper may be ascertained and is useful for implementing an anti-cheat feature, as will be described in more detail herein.

In general, wetness sensor 45 may include any appropriate device operable with the invention and which can detect a wetness event. Sensor variations include devices that can detect threshold levels of, for example, hydrogen ion (OH-), urea, pH, ammonia, and the like. In one implementation, the wetness sensor may generate a signal whenever a threshold level of wetness has occurred, thus indicating an occurrence of a wetness event.

Alternatively, a wetness sensor that generates a continuous signal that indicates that some threshold level of wetness has not been reached may also be used. In this implementation, a wetness event may be detected whenever the wetness sensor has not generated a signal for some predetermined time interval.

Sensors 40 and 45 may be implemented in any of a variety of different manners. For instance, these sensors may be formed as a fine wire mesh or as one or more discrete sensor devices appropriately placed within or on a diaper. Regardless of which type of sensor design utilized, sensors 40 and 45 may be insertable or embedded within an associated diaper. An embedded sensor configuration is typically utilized in conjunction with disposable diapers, whereas an insertable design may be used with disposable, and reusable (e.g., cloth) diapers. Sensors 40 and 45 are shown as discrete components; however, the invention is not so limited and other designs can be utilized where the functionality of these sensors is integrated into a single sensor, if desired.

Typically, communication between the monitoring unit 15 and the sensor unit 20 is accomplished via hardwired electrical components. However, some or all of the communications between these components may be accomplished, if desired, using other signaling technologies such as radio frequencies (RF), infrared (IR), and the like.

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Monitoring unit 15 may be optionally configured with any of a variety of devices to facilitate the monitoring of personal care. For example, the monitoring unit 15 may include one or more sensory alarms 50, a display unit 55, and a data port 60. Sensory alarms 50 are typically utilized to alert a caregiver, for example, that a wetness event has occurred. Typical sensory alarms include auditory alarms, visual indicators such as light-emitting diodes (LED), vibration devices, and the like. A display unit 55 may be utilized to view and recall information associated with the personal care of the person (e.g., infant or incontinent adult) utilizing the device. For example, an appropriate display unit 55 may provide the time, frequency, and duration of a wetness event, as well as the time and elapsed duration of diaper replacement. Appropriately configured systems can record and provide data for a number of wetness events, which is useful for monitoring personal care over an entire day, week, month, or other desired monitoring periods.

In some implementations, the monitoring unit 15 may be configured with a suitable data port 60 to facilitate data communications. The inclusion of a data port 60 enables a user to access and view data obtained during one or more personal care monitoring periods using an appropriately equipped device such a general or specific purpose computer. Data port 60 may be formed using any suitable device such as a serial port, universal serial bus (USB), and the like.

FIG. 1B is a block diagram of an alternative embodiment of the present invention, generally designated 100. Similar to other embodiments, monitoring system 100 generally includes monitoring and sensor units 15, 20. However, in the illustrated embodiment, the monitoring unit 15 is configured with a transmitter 105 to support wireless communications between the unit 15 and externally configured components such as sensory alarms 50 and/or display unit 55. Wireless communication may be accomplished using any suitable signaling technology (e.g., RF, IR, etc.) The monitoring

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unit 15 may also be configured with removable memory 35 and/or a data port 60, if desired.

FIG. 1C is a block diagram of another alternative embodiment of the present invention, generally designated 150. Often, a personal care monitoring system may be utilized to monitor care provided by a caregiver to an infant or infirm adult. In these instances, it may not be necessary or even desirable to enable a caregiver an opportunity to view or access data obtained by the system. To accommodate these needs, a monitoring unit 15 may be implemented without an attached or integrated display unit. In these configurations, the monitoring unit 15 may be outfitted with devices, such as removable memory 35 and/or data port 60, to enable authorized persons (e.g. parents and guardians) an ability to view data obtained during one or more personal care monitoring periods.

FIG. 1C further shows a generalized example of an external display system 160 that may be used in conjunction with monitoring and sensor units 15, 20. As shown, the external display system includes a computer 165 having a display 55 and optional features such as a memory interface 170 and data port 60.

Computer 165 may be any suitable computational device which permits viewing of data obtained in accordance with the invention. As used herein, a "computational device" includes, but is not limited to, personal computers (PC) having an operating system such as DOS, Windows™, OS/2™ or Linux™; Macintosh™ computers; computers having JAVA™ OS as the operating system; graphical workstations such as the computers of Sun Microsystems™ and Silicon Graphics™, and other computers having some version of the UNIX operating system such as AIX™ or SOLARIS™ of Sun Microsystems™; or any other known and available operating system, or any device, including but not limited to: laptops, hand-held computers, personal data assistant (PDA)

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devices, cellular telephones, any type of wireless application protocol (WAP) or short message service (SMS) enabled device, and wearable computers of any sort.

Display 55 may be any suitable display device operable with any of the computing devices described herein. The optional data port 60 may include any suitable device
 5 supporting data communications between the monitoring unit 15 and the computer 165 (e.g., a serial port, universal serial bus (USB), and the like). Similarly, memory interface 170 may be any of a variety of appropriate devices and/or interfaces permitting data retrieval from removable memory 35.

FIG. 2 is a flowchart showing exemplary operations for implementing a personal
 10 care monitoring system according to some embodiments of the present invention and will be described with occasional reference to system 10 shown in FIG. 1A.

By way of example only, the following description of data acquisition in accordance with the invention will reference the following generalized scenario. A parent has outfitted their infant with diapers equipped with a personal care monitoring system in
 15 accordance with an embodiment of the invention. The parent leaves the infant in the custody of a caregiver who provides care over a period of a single day.

As indicated at Block 200, the system may undergo an initialization procedure where routine or necessary procedures are executed or performed as may be required for proper operation. Typical procedures include system checks, memory allocations,
 20 initialization of various system settings. In some embodiments, the initialization procedure will verify that a user is authorized to use or access the system. This verification operation may utilize, for example, a user pass code or other similar user authentication method.

After initialization, control may flow to a human life detection operation, as
 25 indicated in Block 205. This operation may be accomplished using, for example, the

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human life sensor 40. If no human life is detected (e.g., a diaper is not properly placed on the infant), then the time and occurrence of this event may be recorded in the personal care event log, for example, and control may flow back to block 205 to complete an inner loop that continuously or periodically checks for human life. On the other hand, if the
5 presence of human life is detected (e.g., a diaper is appropriately placed on the infant), then the time and occurrence of this event may be recorded in the personal care event log, for example, and control may flow to a wetness event detection operation, as indicated in Block 210.

A wetness event detection operation may be accomplished using, for example, the
10 wetness sensor 45. If a wetness event is not detected, then control may flow back to block 205 to complete an inner loop that continuously or periodically checks for a wetness event, as well as for the presence of human life (e.g. to detect any instances of diaper removal prior to detection of a wetness event). On the other hand, if a wetness event is detected, then the time and occurrence of this event may be recorded in the personal care
15 event log, for example, and control may flow to Block 215 where the wetness duration may be tracked (e.g., the elapsed time that the infant is in contact with a wet diaper). If desired, one or more sensory alarms may also be activated to signal a caregiver of the wetness event.

Tracking the wetness duration is useful to provide parents or guardians with
20 information as to the amount time their infant remains in a wet diaper. Excessive time in a wet diaper may indicate an inattentive or even negligent caregiver.

Control may then flow to a human life detection operation, as indicated in Block 220. If the presence of human life is detected (e.g., the infant continues to have a wet diaper), then control may flow back to Block 215 so that the wetness duration may be
25 continued to be tracked. This operation completes an inner loop that continuously or

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periodically checks for human life. On the other hand, if no human life is detected (e.g., a diaper change is in progress), then the time and occurrence of this event may be recorded in the personal care event log, for example, and control may flow to Block 225 where the diaper off duration may be tracked (e.g., the elapsed time that the infant does not have a
5 diaper).

Tracking the diaper off duration is useful to provide parents or guardians with information as to the amount time their infant remains without a diaper. Excessive time without a diaper may indicate an inattentive or negligent caregiver, or a caregiver who may be attempting to conceal dilatory actions.

10 Control may then flow to another human life detection operation, as indicated in Block 230. If no human life is detected (e.g., a “new” diaper has not yet been placed on the infant), then control may flow back to Block 225 where the diaper off duration may be tracked (e.g., the elapsed time that the infant does not have a diaper). This operation completes an inner loop that continuously or periodically checks for human life. On the
15 other hand, if the presence of human life is detected (e.g., a diaper is appropriately placed on the infant), then the time and occurrence of this event may be recorded in the personal care event log, for example, and control may flow to Block 205 where the just-described operations may be repeated. Notably, each iteration of the operations shown in this flowchart may be associated with a single wetness event. Accordingly, data associated
20 with a plurality of wetness events may be obtained using the illustrated (or other similar) operations.

It is to be understood that in many embodiments, the system performs periodic or continuous checks for human life. This feature not only enables a parent, for example, to track the changing of the infant’s diaper, but also provides a mechanism for preventing
25 system tampering or manipulation by a caregiver attempting to conceal negligent care.

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Although the present invention may be implemented using the exemplary series of operations shown in FIG. 2, those of ordinary skill in the art will realize that additional or fewer operations may be performed. Moreover, it is to be understood that the order of operations shown in FIG. 2 is merely exemplary and that no single order of operation is
5 required or necessary.

FIGS. 3A and 3B are block diagrams showing some of the many configurations possible for implementing the present invention. In particular, FIG. 3A depicts a disposable or reusable diaper 80 having human life and wetness sensors 40, 45 which are in communication with a monitoring unit 15.

10 In some embodiments, sensors 40, 45 may be manufactured as low-cost disposable devices, while in other embodiments these sensors are reusable. Similarly, monitoring unit 15 can be fabricated as a disposable or reusable device to accommodate a user's particular need. Because these sensors and monitoring units may be configured to cooperate with disposable and reusable (e.g., cloth) diapers, a wide variety of
15 implementations are possible. Accordingly, the present invention may be implemented using any combination of disposable/reusable sensors, monitoring units, and diapers.

For example, in a completely disposable implementation, diaper 80 may be fabricated having disposable human life and wetness sensors 40, 45, and configurable with a disposable monitoring unit 15. In these configurations, the monitoring unit 15 may
20 be attached (or attachable) to the sensors 40, 45 in a manner depicted in FIG. 3A.

Alternatively, as shown in FIG. 3B, the monitoring unit 15 may be completely integrated with the diaper 80. Completely integrated embodiments often include removable memory
35 so that personal care data may be retrieved by, for example, a parent or guardian. Other disposable embodiments include disposable sensors 40, 45 fabricated as discrete
25 components adaptable to any of variety of diaper types. These implementations are useful

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when personal care monitoring is desired using readily available, off-the-shelf diapers.

FIGS. 4A and 4B are more detailed views of possible sensor implementations according to some embodiments of the invention. For example, FIG. 4A depicts a diaper 80 configured with a wire mesh wetness sensor 45. In this example, a human life sensor 40 may be positioned at opposing ends of the diaper 80. Although the wire mesh wetness sensor 45 may be disposed on (or integrated within) a portion of the diaper 80, the exact positioning or size of the sensor is not critical to the invention. For example, FIG. 4B shows still another alternative design where the wetness sensor 45 occupies a centralized portion of the diaper 80. This centralized portion is often associated with the portion of a diaper most likely to experience a wetness event. It is therefore to be understood that the invention may be implemented using any of a variety of different sensor configurations, sizes, and geometries.

FIG. 5 is a diagram of a monitoring system having several integrated features in accordance with some embodiments of the present invention. As shown, a monitoring unit 15 generally includes a display unit 55, sensory alarms 50, and a user interface 85. The monitoring unit 15 is shown in communication with diaper 80 and associated human life and wetness sensors 40, 45.

Sensory alarms 50 are shown implemented as a wetness buzzer and light, but additional or fewer sensory alarms may be used as desired. The user interface 85 may also include any of a variety of useful devices that permits or facilitates user/system interaction. Typical user interfaces include, for example, facilities enabling one to retrieve person care data, activate/deactivate the monitoring system, and the like. In some implementations, a predetermined or user definable pass code may be required to access one or more functions of the monitoring system. Utilization of a pass code is useful for those who wish to use the system to reliably monitor the level of care provided by a

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caregiver. Since the pass code may be known only to the parent, the caregiver may not be able to readily access data acquired by the system, thus preventing system tampering by, for example, a caregiver wishing to conceal improper or negligent care.

FIG. 6 shows one of the many configurations possible for implementing display unit 55 in accordance with the present invention. It is to be understood while the illustrated features are representative of typical implementations, no particular feature, or configuration of features, is essential or required.

In some embodiments, display unit 55 may generally include a series of events 90 and associated data displays 95. The series of events 95 relate to events that a user may desire tracking so that personal care of an individual may be monitored or assessed. FIG. 6 provides a representative list of the many possible events that may be tracked and monitored in accordance with the invention, but additional or fewer events may be tracked if desired.

The base start time may be used to indicate when the monitoring system has been activated. An example of system activation may be when care of an infant is turned over to a caregiver. In this scenario, the parent may activate the system by, for example, entering a required pass code. As indicated in FIG. 6, the monitoring system was activated at 8:00 A.M.

A wetness indicator may be used to track data associated with one or more wetness events. For example, it is not uncommon for an infant to have many wetness events over the course of a typical day. As such, a parent may want to track the quality of care provided by the caregiver for each of these wetness events. The first wetness event is depicted in this Figure.

The time of occurrence of a wetness event and when the diaper is eventually changed can also be displayed. In the example, a wetness event was detected at 9:15

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A.M., and the diaper was changed at 9:35 A.M., indicating that the infant remained in a wet diaper for 20 minutes. This caregiver replaced the diaper at 9:45 A.M., resulting in the infant being without a diaper for 10 minutes. Excessive elapsed wet time or excessive diaper off time may indicate negligent care provided by the caregiver.

5 The display unit 55 may be formed using any suitable display technology (e.g., LCD, LED). In some embodiments, a single display is utilized, while in other embodiments some or all of the events 95 may include individual display units. Still further implementations for display unit 55 have been described with respect to FIG. 1C.

FIG. 7 is an example of the types of data that may be acquired and provided in
10 accordance with the invention. This data is referred to generally as a personal care event log, and may be stored and retrieved using any of the aforementioned memory devices shown and described in FIGS. 1A-1C.

As depicted in FIG. 7, a personal care event log may include, for example, data associated with a number of wetness events and associated "diaper off" instances. The
15 personal care event log is shown with data relating to three separate wetness events, and is capable of supporting data associated with up to N distinct wetness events. Typically, the personal care data log contains wetness event data information relating to a single day, but may easily be adapted to include data over several weeks or even months.

As indicated in the event log, the caregiver appeared to be relatively diligent in
20 providing care to the infant for the first two wetness events, but then failed miserably in the third wetness event. For example, during the first two wetness events, the infant remained in a wet diaper for 20 minutes and 6 minutes, respectively. Thus, it appears that the caregiver is proving an acceptable level of care. However, after the third wetness event (11:42 A.M.), the infant remained in wet diaper for 126 minutes (until 1:48 P.M.),
25 thus indicating negligence and lack of care provided to the infant.

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FIG. 8 is an exploded perspective view of an exemplary monitoring unit in accordance with some embodiments of the invention. Monitoring unit 15 is shown having upper and lower housings 300, 305 which may be used to contain an electronics module 310. The electronics module 310 is shown having a system controller 25, sensor port 47, several sensory alarms 50, a display unit 55, and a user interface 85. Access to the sensor port 47 is facilitated by port cut-outs 320, 325 respectively formed in upper and lower housings 300, 305.

Sensory alarms 50 are shown implemented as a wetness alarm and two individual LEDs attached to an upper surface of the electronics module 310. If desired, auditory holes 315 may be formed in the lower housing 305, proximate to the wetness buzzer 50, to facilitate sound propagation.

The user interface 85 is shown implemented as four discrete buttons formed on the electronics module 310. Access to the user interface 85, once assembled, may be accomplished via user interface cut-outs 335 formed on the upper housing 300. Similarly, LED cut-outs 340 may be used to expose LED sensory alarms 50. The monitoring unit 15 may be powered by any suitable power source, such as battery 330. Again, the monitoring unit shown in FIG. 8 is but one example of the many possible implementations and embodiments of the invention, and is shown having many optional features that are not required or essential.

FIGS. 9A and 9B are perspective views showing, respectively, partially assembled and assembled views of the exemplary monitoring unit of FIG. 8. In FIG. 9A, the electronics module 310 is shown positioned within the lower housing 305. FIG. 9B depicts the monitoring unit 15 as it may appear after assembly.

FIGS. 10A through 10C are top, front, and side views, respectively, of an assembled monitoring unit of FIG. 8. These Figures provide an illustration of the relative

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relationship of some of the features that may be included with the monitoring unit 15. For example, the sensory alarms 50 (e.g., LEDs), display unit 55, and user interface 85 buttons can be seen in the top view of FIG. 10A, while the sensor port 47 is viewable in the front view of FIG. 10C.

5 An appropriately configured personal care monitoring system may be utilized or implemented in a variety of different manners including child care facilities, hospitals, nursing homes, private home care, “nanny watch” services, remote monitoring systems, and the like. Those who may also benefit from the use of such systems include concerned parents, healthcare industries, medical and hospital organizations, as well as those
10 providing convalescent and hospice care.

 While the invention has been described in detail with reference to disclosed embodiments, various modifications within the scope and spirit of the invention will be apparent to those of working skill in this technological field. It is to be appreciated that features described with respect to one embodiment typically may be applied to other
15 embodiments. Therefore, the invention properly is to be construed with reference to the appended claims.

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Claims

What is claimed is:

1. A personal care monitoring system comprising:
 - 2 a wetness sensor (45) configured to detect a wetness event occurring within an
associated diaper (80);
 - 4 a human life sensor (40) configured to detect a presence of human life relative to
said associated diaper; and
 - 6 a monitoring unit (15) comprising a system controller (25) in communication with
said wetness and human life sensors, wherein said system controller monitors said
8 wetness and human life sensors and generates data associated with detected wetness
events and presence of human life relative to said associated diaper.
2. The personal care monitoring system according to claim 1, said system
2 further comprising:
 - an external display unit (55) adapted to display said generated data associated with
4 said detected wetness events and presence of human life; and
 - a wireless transmitter (105) configured with said monitoring unit and in
6 communication with said system controller, wherein said wireless transmitter facilitates
communications between said monitoring unit and said external display unit, wherein said
8 communications includes said generated data associated with said detected wetness events
and presence of human life.
3. The personal care monitoring system according to claim 2, wherein said
2 wireless transmitter facilitates communications between said monitoring unit and an
external sensory alarm (50), wherein said external sensory alarm is responsive to a
4 detection of a wetness event.

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4. The personal care monitoring system according to claim 1, said system
2 further comprising:
removable memory (35) configured with said monitoring unit and in
4 communication with said system controller, wherein said removable memory comprises
said generated data associated with said detected wetness events and presence of human
6 life.

5. The personal care monitoring system according to claim 1, wherein said
2 wetness and human life sensors are integrated into a single sensor device.

6. The personal care monitoring system according to claim 1, wherein said
2 wetness and human life sensors are at least partially embedded within said associated
diaper.

7. The personal care monitoring system according to claim 1, wherein said
2 wetness and human life sensors are disposed onto said associated diaper.

8. The personal care monitoring system according to claim 1, said system
2 further comprising:
a sensory alarm (50) configured with said monitoring unit and in communication
4 with said system controller, wherein said sensory alarm is responsive to a detection of a
wetness event.

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9. A wearable article operable with a personal care monitoring system, said
2 article comprising:
a diaper (80) comprising a liquid impermeable layer having an interior surface and
4 an exterior surface;
a wetness sensor (45) configured with said diaper, wherein said wetness sensor is
6 adapted to detect a wetness event occurring within said diaper;
a human life sensor (40) configured with said diaper, wherein said human life
8 sensor is adapted to detect presence of human life relative to said diaper; and
wherein said wetness and human life sensors are adapted to responsively
10 communicate to an associated personal care monitoring unit (15), detected wetness events
and presence of human life relative to said diaper.

10. The article according to claim 9, wherein said personal care monitoring
2 unit is detachably connected to said diaper.

11. The article according to claim 9, wherein said personal care monitoring
2 unit is integrated with said diaper, and wherein said monitoring unit includes removable
memory (35) comprising data associated with said detected wetness events and presence
4 of human life.

12. The article according to claim 9, wherein said wetness and human life
2 sensors are integrated into a single sensor device.

13. The article according to claim 9, wherein said wetness and human life
2 sensors are at least partially embedded within said interior surface of said diaper.

14. The article according to claim 9, wherein said wetness and human life
2 sensors are disposed onto said interior surface of said diaper.

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15. A personal care monitoring system comprising:
2 a means for detecting a wetness event (45) occurring within an associated diaper
(80);
4 a means for detecting a presence of human life (40) relative to said associated
diaper; and
6 a means for monitoring (15) and controlling (25) said wetness event detecting
means and said presence of human life detecting means, wherein said monitoring and
8 controlling means generates data associated with detected wetness events and a presence
of human life relative to said associated diaper.

16. The personal care monitoring system according to claim 15, said system
2 further comprising:
displaying means (55) configured with said monitoring and controlling means,
4 wherein said means for displaying is adapted to display said generated data associated
with said detected wetness events and presence of human life.

17. The personal care monitoring system according to claim 15, said system
2 further comprising:
removable memory means (35) configured with said monitoring and controlling
4 means, wherein said removable memory means comprises said generated data associated
with said detected wetness events and presence of human life.

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18. A personal care monitoring system comprising:

- 2 a wetness sensor (45) configured to detect a wetness event occurring within an
associated diaper (80);
- 4 a human life sensor (40) configured to detect a presence of human life relative to
said associated diaper;
- 6 a monitoring unit (15) comprising a system controller (25) in communication with
said wetness and human life sensors, wherein said system controller monitors said
8 wetness and human life sensors and generates data associated with detected wetness
events and presence of human life relative to said associated diaper; and
- 10 a display unit (55) configured with said monitoring unit and in communication
with said system controller, wherein said display unit is adapted to display said generated
12 data associated with said detected wetness events and presence of human life.

19. The personal care monitoring system according to claim 18, said system
2 further comprising:
- a sensory alarm (55) configured with said monitoring unit and in communication
4 with said system controller, wherein said sensory alarm is responsive whenever a
threshold amount of time has elapsed where no presence of human life relative to said
6 associated diaper has been detected by said human life sensor.

20. The personal care monitoring system according to claim 18, wherein said
2 system controller responsively provides data to said monitoring unit indicative of any
instances where no presence of human life relative to said associated diaper has been
4 detected by said human life sensor.

21. The personal care monitoring system according to claim 18, said system
2 further comprising:
- a user interface (85) configured with said monitoring unit and facilitating retrieval
4 of said generated data associated with said detected wetness events and presence of
human life.

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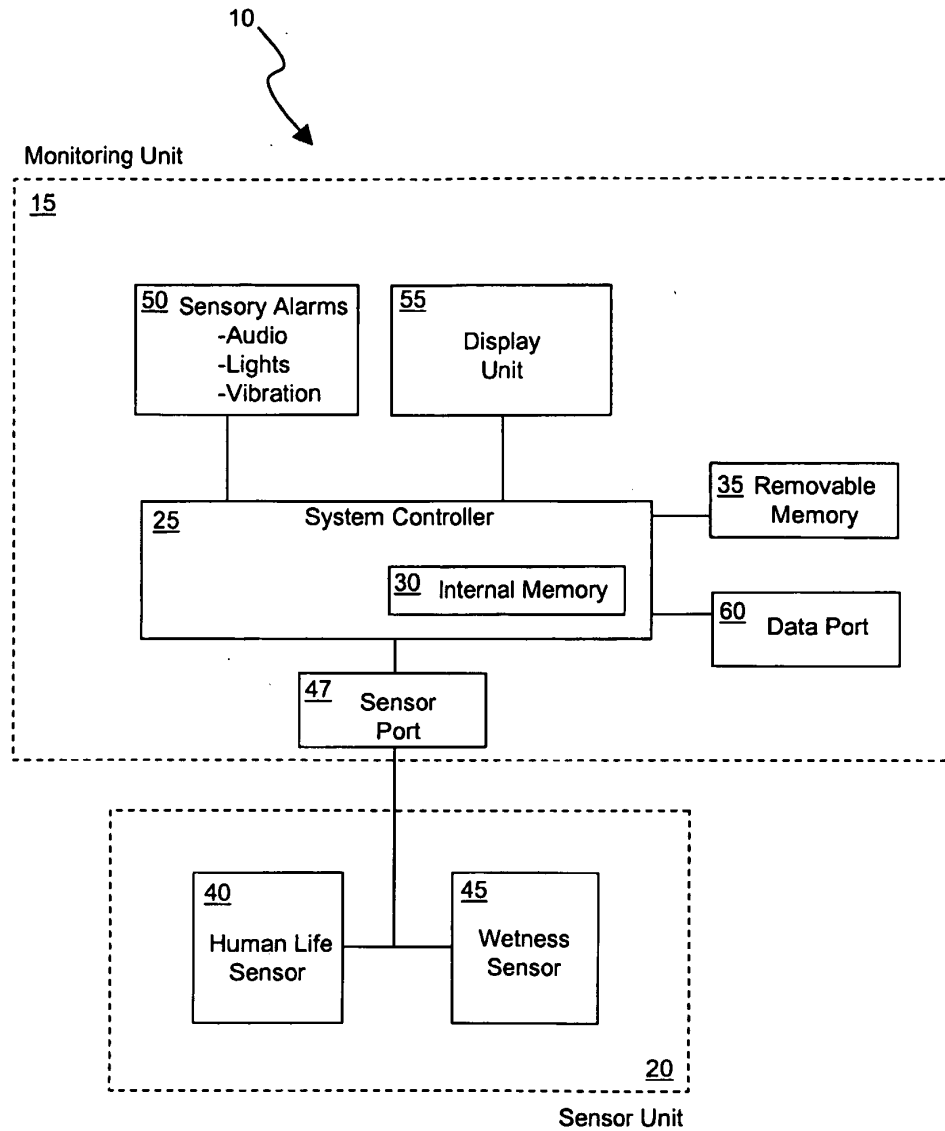


FIG. 1A

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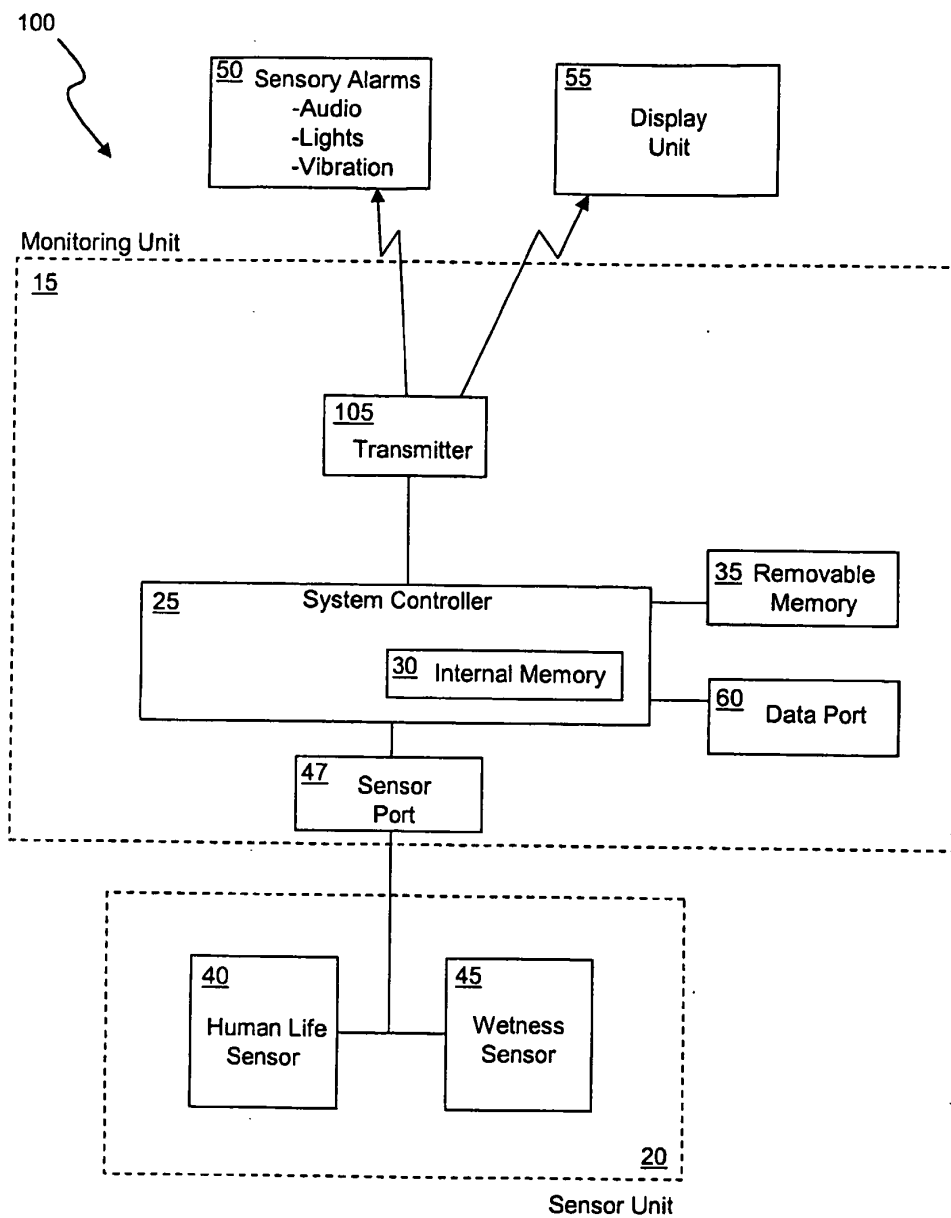


FIG. 1B

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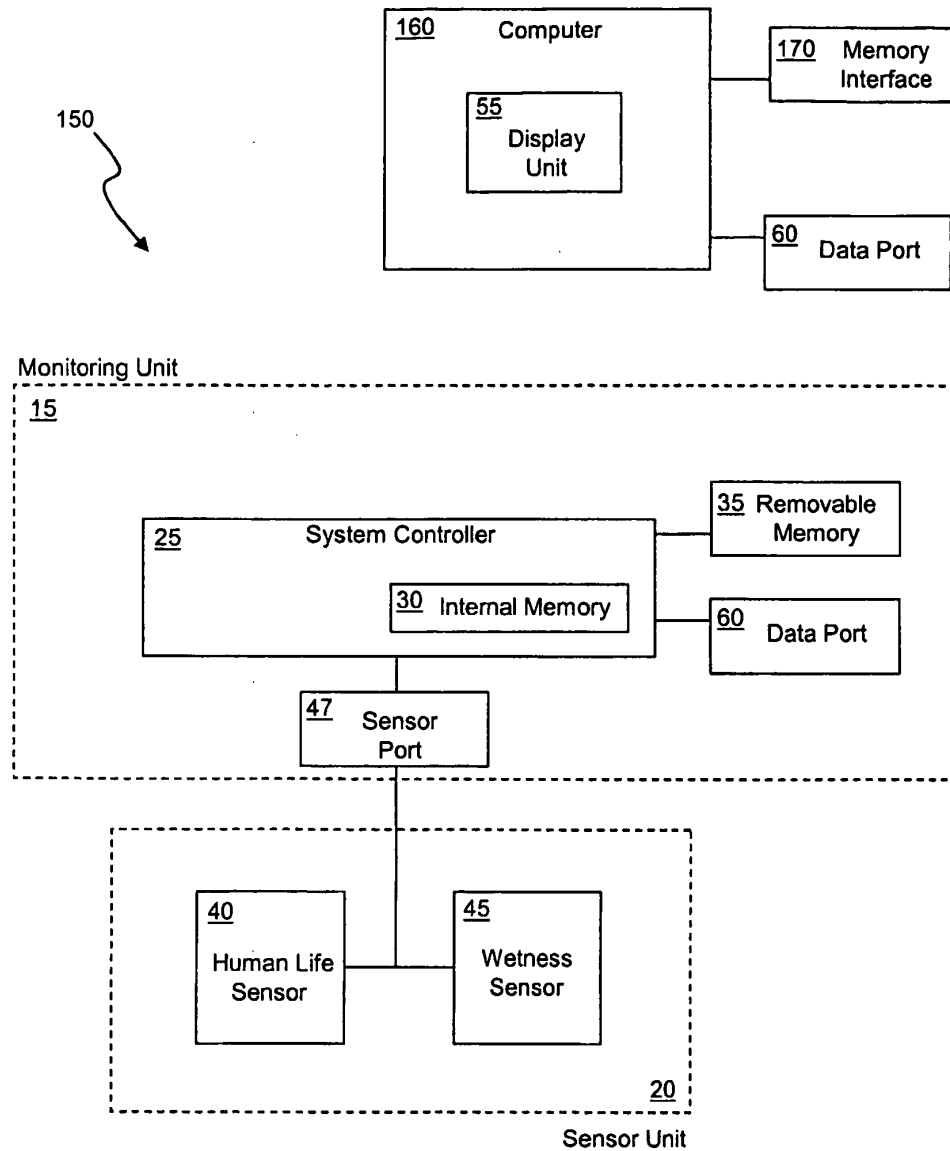
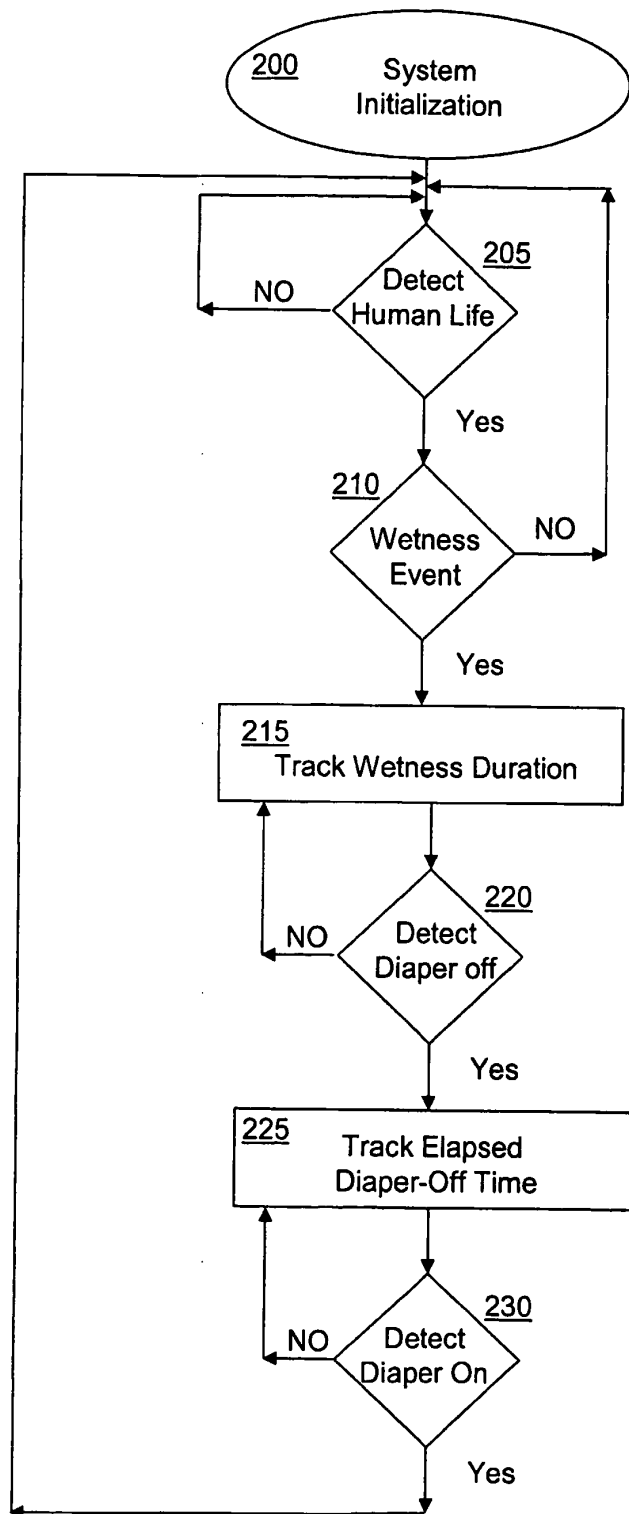


FIG. 1C

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**FIG. 2**

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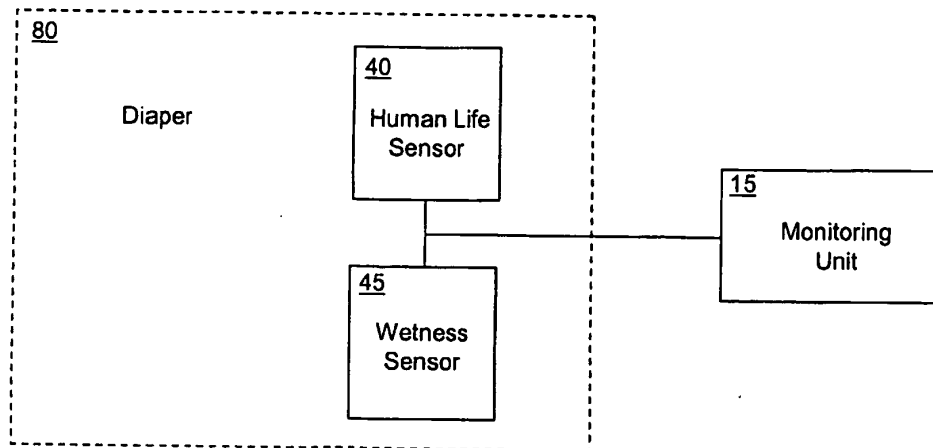


FIG. 3A

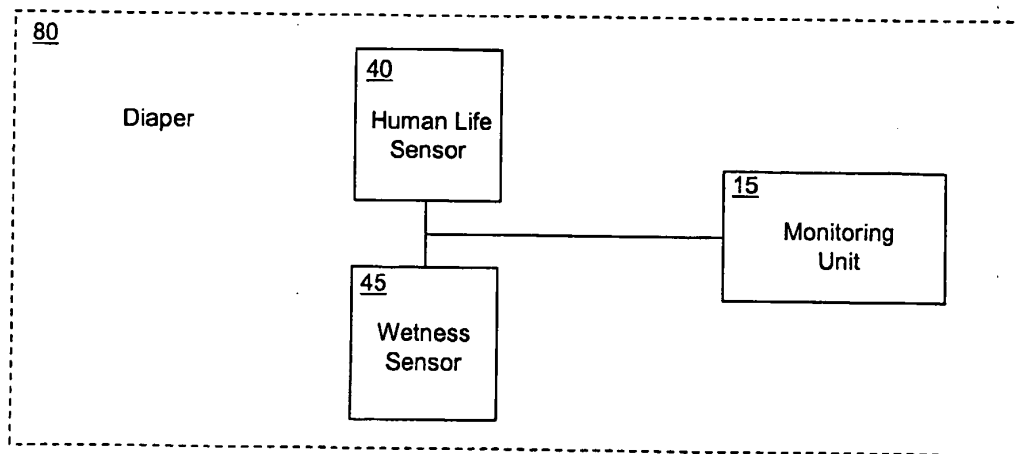


FIG. 3B

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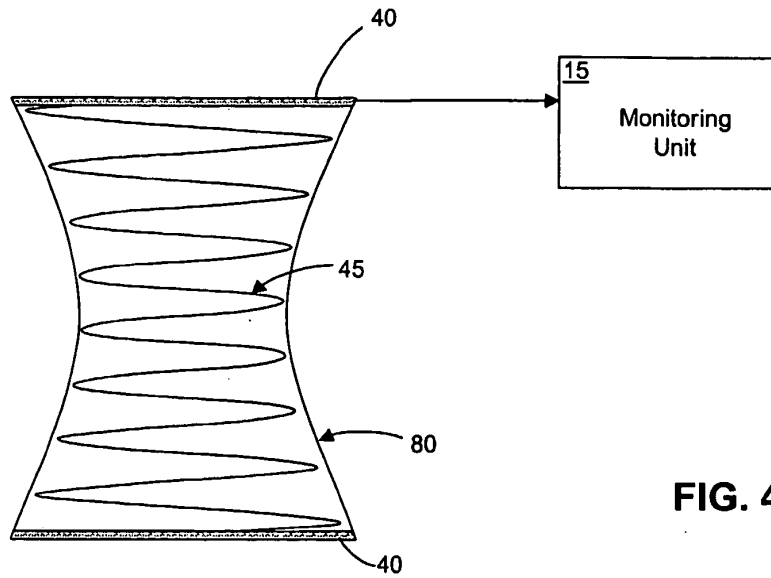


FIG. 4A

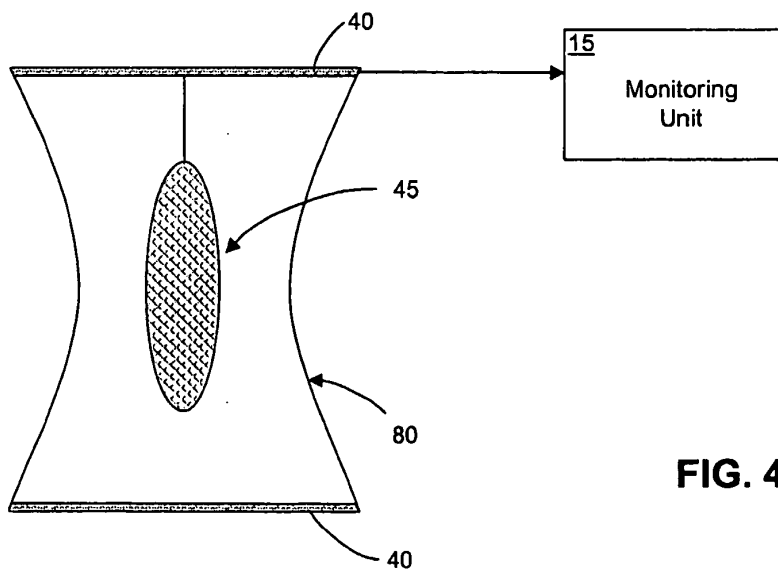


FIG. 4B

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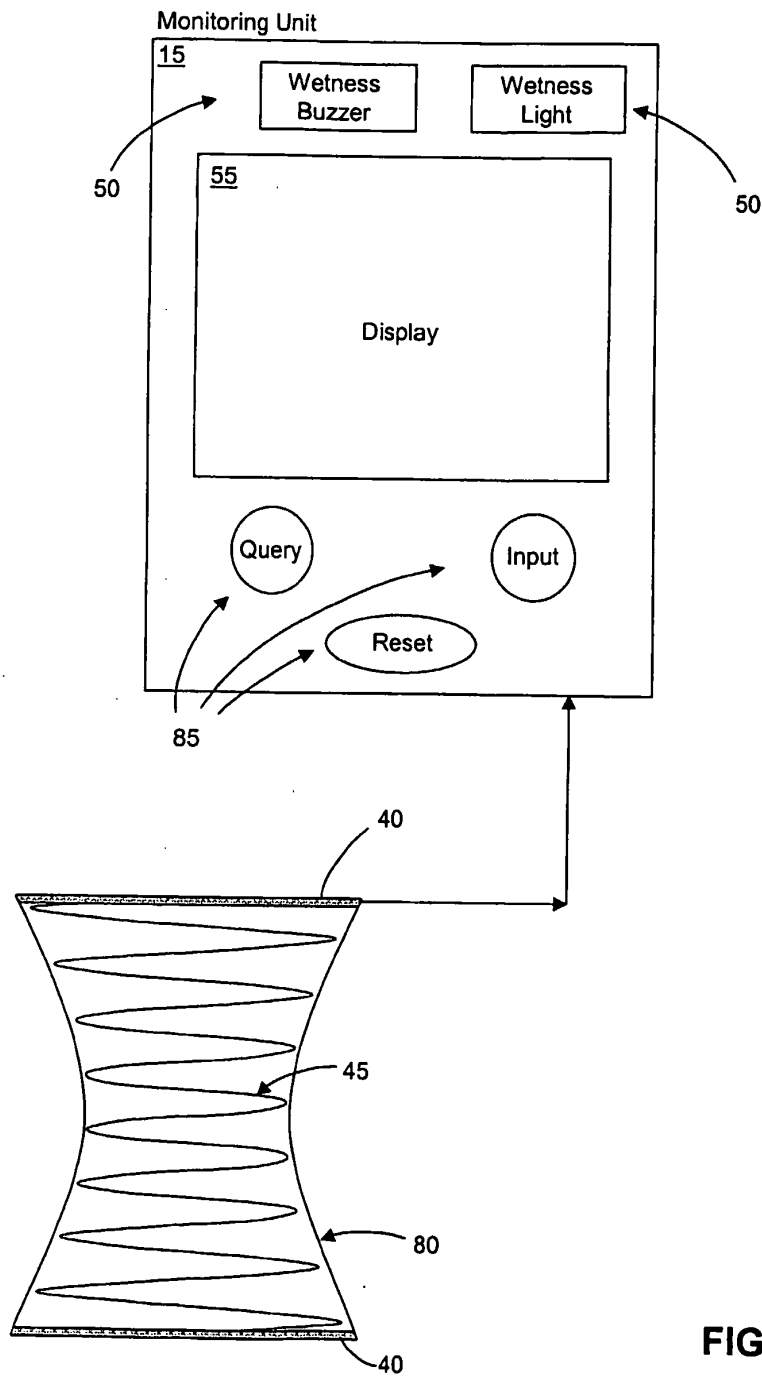


FIG. 5

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90

95

Display

55

Base Start Time	8:00 A.M.
Wetness Event Number	One
Wetness Detected	9:15 A.M.
Wetness End Time (diaper off)	9:35 A.M.
Elapsed Wet Time	20 Min.
Diaper Replaced	9:45 A.M.
Elapsed Diaper Off	10 Min.

FIG. 6

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Personal Care Event Log

	1	2	3	...	N
Base Start Time	8:00 A.M.	8:00 A.M.	8:00 A.M.
Wetness Event Number	One	Two	Three	...	N
Wetness Detected	9:15 A.M.	10:12 A.M.	11:42 A.M.
Wetness End Time (diaper off)	9:35 A.M.	10:18 A.M.	1:48 P.M.
Elapsed Wet Time	20 Min.	6 Min.	126 Min.
Diaper Replaced	9:45 A.M.	10:23 A.M.	1:55 P.M.
Elapsed Diaper Off	10 Min.	5 Min.	7 Min.

FIG. 7

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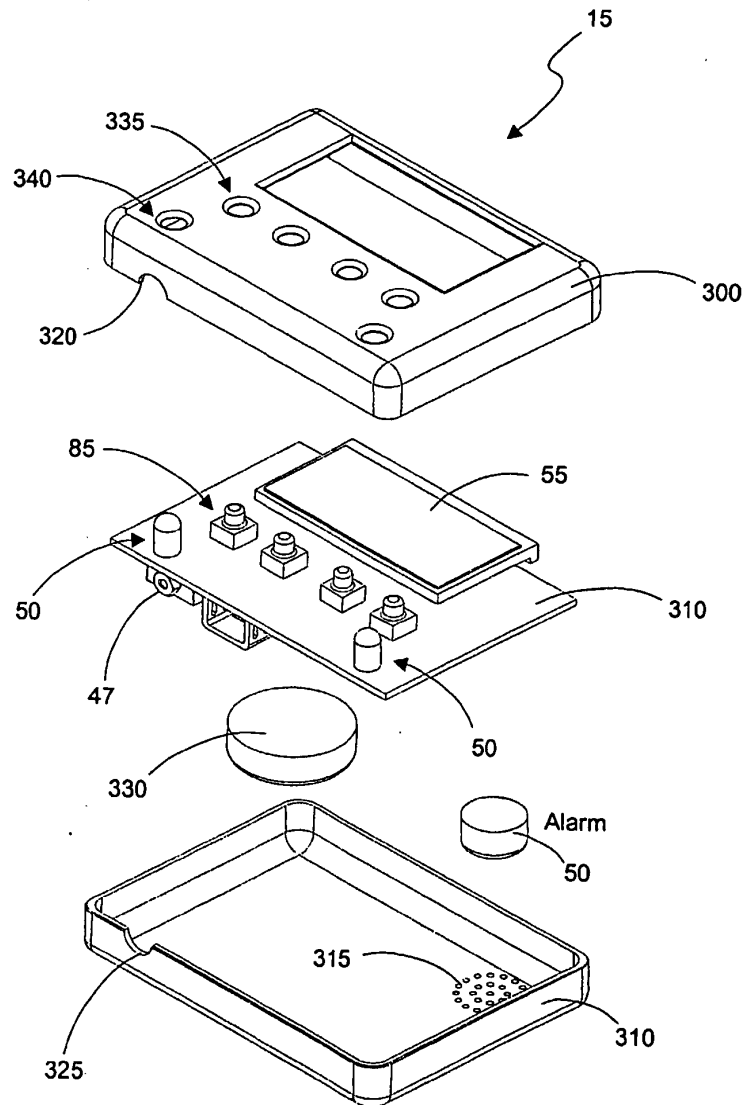


FIG. 8

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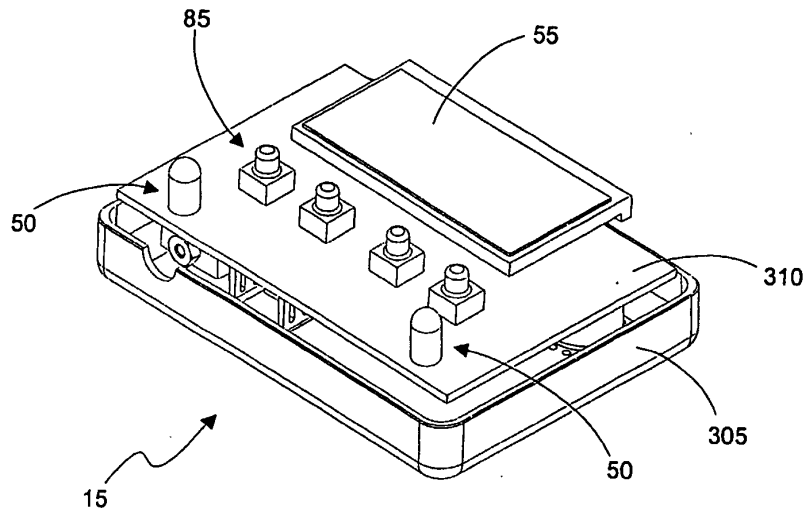


FIG. 9A

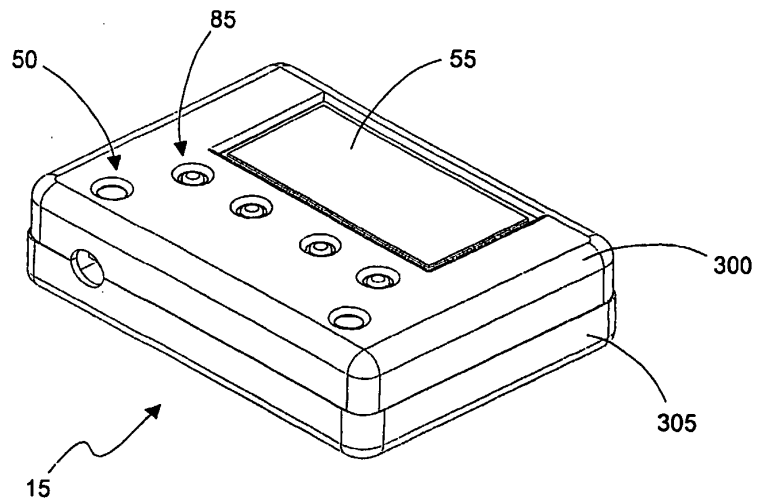
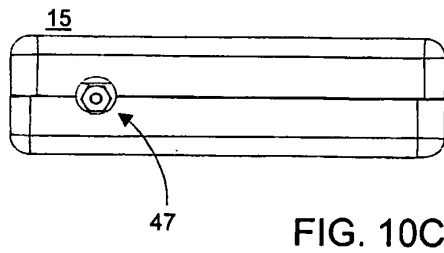
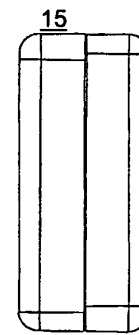
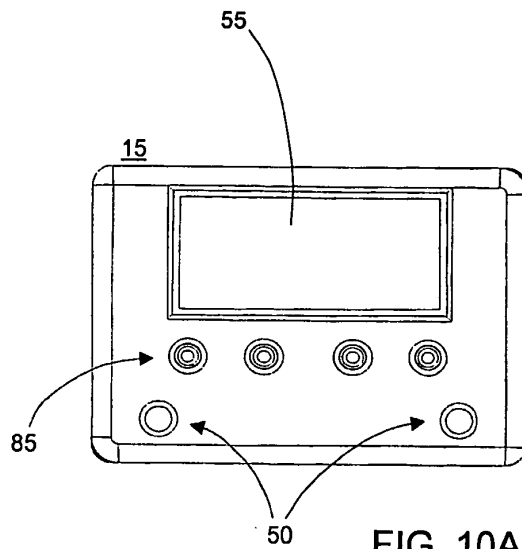


FIG. 9B

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— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INCONTINENCE SENSOR

(57) Abstract: A body fluid sensor for remote volume reading of expelled fluid, e.g., urine, is disclosed. A bottom layer has a conductor pattern of separate electrodes extending a given length in closely spaced relationship. An apertured sheet covers over said layer and the conductor pattern with plural apertures aligned with the electrodes over the given sensing length at staggered intervals thereof. A fluid absorbent skin covers the apertured sheet allowing fluids applied to the skin to migrate through one or more of the apertures forming an electrical bridge of a resistance characteristic of the fluid between the electrodes.

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INCONTINENCE SENSOR

5 CROSS REFERENCE TO RELATED APPLICATIONS

This application claims the priority of U.S. Provisional Application No. 60/419,581 filed October 18, 2002 entitled, INCONTINENCE SENSOR, the whole of which is hereby incorporated by reference herein.

10

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

N/A

15

BACKGROUND OF THE INVENTION

Urinary incontinence or enuresis can be an embarrassing and highly inconvenient problem for children and older adults. For children, bed-wetting beyond the age when most other children have achieved nocturnal bladder control is the most frequent
20 manifestation. For older adults, the problem can range from minor leakage upon sneezing or coughing to complete incontinence for nursing home patients.

Children achieve bladder control at different ages. By the age of five years, most children no longer urinate in their sleep.
25 However, more than five million children in the United States alone continue to wet the bed past the age of six. The exact cause of bed-wetting is not known. Many factors are involved. In some children, the cause may be genetic (bed-wetting tends to run in families). In other children, nighttime bed-wetting may occur
30 because more urine is produced during sleep. Another cause of bed-wetting may be a small bladder and its inability to hold urine for a long time. A less common cause of bed-wetting may be a problem with the bladder, the kidneys or the nervous system. Deep

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sleep is not thought to be a cause of bed-wetting. However, deep sleep may prevent a child from responding to the signal from the bladder of a need to urinate. For adults, enuresis is more likely to be caused by a loss of sphincter control, which may be minor or
5 more serious. In this type of situation, the adult can be unaware of the leakage of urine.

As an aid for managing enuresis in both children and adults, moisture alarms or incontinence sensors can be very helpful. Many families have found that use of a nighttime moisture alarm enables
10 parents to help a child wake up and void in the bathroom. Eventually, the child can learn to wake up on his or her own without the alarm or even to sleep through the night while remaining dry. Adults can use a moisture detector with a private alarm so that they can be aware of the leakage before more
15 extensive wetting occurs. For those adults who are incontinent and rely on the help of others, the moisture alarm can be configured for remote notification of the caregiver.

Existing sensor devices come in a variety of sizes and configurations. For example, one type of device is gold plated
20 and the size of a postage stamp. This device is designed to be worn within the clothing of the subject and is washable and long-lasting. It can be configured for wired or wireless notification of either the wearer or a remotely located caregiver. Other available devices are configured for use in a bed. One type is a
25 foil embossed plastic mat that fits between the sheets and on top of the mattress. Another type of sensor is a three layer absorbent pad consisting of a soft absorbent top cover, an absorbent inner filling and a lower moisture barrier. In this device, the electrical sensor is a pair of conductive fabric
30 strips sewn into the pad above the fill layer, and the presence of urine, which has a relatively high salt content, is detected by measuring the resistance between the conductive strips. This device, which does not detect plain water, is described as being

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machine washable or dry cleanable. However, there still exists a need for additional types of incontinence sensors that would provide broader flexibility to the user.

5 BRIEF SUMMARY OF THE INVENTION

These and other goal are accomplished in the embodiments of the invention providing a body fluid sensor for remote volume reading of the presence and volume of body fluids in a patient environment. In the sensor, a first layer provides support for
10 and has on it a conductor pattern having at least a first electrode of at least a given length and a second electrode of at least said given length. The first and second electrodes extend the given length in closely spaced relationship to define a sensing length between them.

15 The electrodes are electrically isolated one from the other and extend to connection terminals at one periphery of the sensor.

These provide electrical contact external of said sensor to interface and processing electronics which can further include a central patient monitoring station that displays messages and
20 warnings indicative of the presence and volume of sensed body fluids.

An apertured cover sheet is adhered over the first layer and the conductor pattern thereon and has plural apertures aligned with the sensing length at staggered intervals. A fluid absorbent
25 skin is applied over the cover sheet whereby fluids applied to the skin migrate through one or more of the apertures of the cover to provide an electrical bridge of a resistance characteristic of the fluid between electrodes.

The processor and interface signals the sensor to read
30 resistance. In an embodiment where additional electrodes are provide with additional connector terminals, the size and dimensions of the sensor and its intended use are communicated. These goals are achieved by use of a conductor pattern applied

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with a partially conductive or semi-conductive ink applied in regions independent of the fluid sensing areas so the resistance is a size indicator. An additional ink element can be deposited in an area away from the fluid sensing area with predetermined resistance indicative of the use of the sensor.

The incontinence sensor assembly according to the invention is simple and inexpensive to manufacture in various configurations. It is comfortable to use and operate and is designed to be disposable.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Other features and advantages of the invention will be apparent from the following description of the preferred embodiments thereof and from the claims, taken in conjunction with the accompanying drawings, in which:

Fig. 1 is a side view of an incontinence sensor assembly according to the invention;

Fig. 2a is a plan view of the circuit layer of multiple incontinence sensors of the invention according to Fig. 1;

Fig. 2b is another embodiment of the circuit layer of an incontinence sensor according to the invention;

Fig. 3 is a plan view of the die cut adhesive layer of multiple incontinence sensors of the invention according to Fig. 1; and

Fig. 4 is a circuit diagram of the incontinence sensor of Fig. 1.

DESCRIPTION OF THE PREFERRED EMBODIMENT OF THE INVENTION

In one embodiment, the incontinence sensor of the invention is used in conjunction with a Patient Activity Monitoring System as described in co-pending Application No. _____, filed this day, entitled Patient Activity Monitor, the whole of which is

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incorporated by reference herein. A Patient Activity Monitoring System allows caregivers of multiple patients to work more efficiently and with reduced cost, while increasing the quality and level of patient care.

5 The incontinence sensor according to the invention is exemplified herein by two sensor configurations, which differ in their physical dimensions. A wheelchair incontinence sensor is in the form, e.g., of a thin strip, e.g., 7/8" x 12" x less than 1/64", which can be laid down on a wheelchair seat or among the
10 patient's wheelchair pads. A bed incontinence sensor is physically in the form, e.g., of a two-dimensional pad covering the appropriate portion of the bed of the user. In one version, a sensor strip similar in configuration to that used for a wheelchair runs diagonally across the pad. In another version, the
15 elements of the sensor circuit are designed to occupy the major portion of the pad. In all configurations, the incontinence sensor of the invention provides an indication of the "area of wetness" sensed.

As will be described in more detail below, when in use with
20 the Patient Activity Monitoring System, the incontinence sensor is plugged in at the smart sheet sensor remote monitoring unit. (The connection point is adjacent to the smart sheet connection point, which provides patient activity feedback.) The incontinence sensor is connected to the monitoring unit with a common telephone jack
25 and its connection detected by the monitoring unit electronics via a sensor configuration bit. The electronics then determines a dry resistance reading, which can be associated with and indicative of different sensor configurations, e.g., as a wheelchair or bed sensor, or different sensor shapes. The configuration
30 determination also indicates that the sensor is connected to the reading electronics.

The incontinence sensor incorporates a variable resistor (as will be described in detail below), the resistive value of which

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is read by one of several, e.g., A to D, inputs of a micro-controller in the monitoring unit, or processor. The measurable resistive range of the sensor is generally between 10M ohms (typical dry resistance) and 130K ohms for the wheelchair configuration. This resistive range accommodates various areas of wetness of the sensor. The sensor can be made in different lengths and widths, but the measured resistance of a 100% wet (e.g., urine) sensor is typically set to be near 130K ohms. Due to the sensor design, the decrease in resistance is a function of the percent wetness. The volume creating the wetness for different sensor lengths can be calculated by calibrating the sensor dimensions in processor memory to the start of resistance change. The sensor length can always be calculated by using an additional circuit electrode pattern of known unit resistance so that an applied signal, which travels the length of the sensor and back, indicates the total resistance of the sensor.

Referring to Fig. 1, a side view of a preferred embodiment, it can be seen that an incontinence sensor of the invention 10 includes a 0.010" thick, typically polyester sensor sheet layer 15 on which is laid down a carbon ink, or other semiconductive or partially conductive circuit 20, described in detail below; a die cut adhesive layer 30 (3M Company No. 467) over the sensor circuit layer; and a thin absorbant sheet layer 40 (e.g., Crane & Company S-10 cotton Saturating Base Paper, 0.010" thick) over the die cut adhesive layer, which is placed next to the patient or wearer. On the underside of sensor sheet 15 is a medium tack adhesive layer 42, which provides for easy release of the sensor from clothes or bedding after use, and a release paper cover layer 44, which is removed prior to sensor use so as to expose the tack adhesive layer. Circuit 20 is connected to a two wire telephone cable lead 46, in the embodiment of Fig. 2a, via a connection 48 such as crimped pins or soldering, and padded with protective tape 50.

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Lead 46 is terminated with a standard four pin telephone jack 52, for connecting with a processor 25 having a resistance interface.

Fig. 2a is a plan view of multiple versions of sensor 10 showing circuits 20, which are laid down on polyester sensor sheet strips 15. As shown in Fig. 2a, multiple versions of the sensor can be manufactured simultaneously in one sheet, and then the sensors can be separated. An individual circuit 20 consists of semiconductive or partially conductive elements 22 and 24, having end terminals 21 and 23, respectively, that are electrically isolated from each other. Portions of elements 22 and 24 are formed as parallel adjacent thin lines, which are very closely spaced but not touching, arrayed along one edge of each sensor strip 15. In Fig. 2b, an alternative embodiment of the circuit 20" is shown in which interdigitating circuit elements 22" and 24" occupy a two dimensional, substantially rectangular, area. A sensor having this circuit configuration is particularly suitable for covering large areas, e.g., as a bed incontinence sensor.

Fig. 3, also a plan view of the embodiment of Fig. 2a, shows adhesive layers 30 of sensors 10 laid down on top of circuits 20. As can be seen in Fig. 3, in each sensor 10, multiple die cut apertures 32 are made in the adhesive layer 30 to expose adjacent segments 22' and 24' on circuit elements 22 and 24 and serve as "wick wells" for absorbent sheet 40.

The sensor is attached, e.g., to a wheelchair pad or bedsheet sensor by peeling back the release paper 44 to expose the medium tack adhesive 42 and then pressing it to the wheelchair or bedsheet sensing pad. In operation, fluid wicking into or absorbed by absorbent sheet 40 migrates into individual die cut apertures 32 and forms a resistive bridge between each of the conductor circuit segments 22' and 24' at each aperture 32 where there is liquid. In effect, this causes the resistance between the end terminals 21, 23 to decrease a predetermind quantum for each aperture where a resistive bridge is created between circuit

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segments 22', 24'. A linear change reflective of the fluid volume (the wetted length of the sensor) is thus produced, making a simplified measurement by a processor 25 of not only the presence of a body fluid (urine in the case of an incontinence sensor) but
5 also its volume.

In the embodiment of Fig. 4, shown here in the form of a circuit diagram, a sensor is designed having four external connections 31, 33, 35, 37. Connections 31 and 33 connect via inked patterns to a length of facing conductor elements in region
10 39, such as provided by conductor elements 22 and 24 (Fig. 2), and in which region the migration of fluid causes a resistive bridging therebetween. Additional connections 35 and 37 allow for the measurement of further indicia by the processor 25. For example, a printing of ink of a specified width and/or depth in a region 41
15 between connections 35 and 37 can impart a predetermined resistance that can be read by processor 25 to reflect various characteristics of the sensor such as size, one or two dimensional extent of the circuit pattern, and/or intended use including bed or wheelchair use. In this case, it is preferable for the inked
20 conductive pattern to have a resistivity greater than that of the connections to the processor so that the resistance can be used for this measurement. Additionally, the resistance between connections 31 and 37 can be used to indicate the length of the sensor from the resistance of the conductive (partially or semi)
25 pattern between them. This resistive measurement, furthermore, is an indication that the sensor is actually connected to the processor.

Referring again to Fig. 1, it can be seen that sensor assembly 10 is connected by telephone jack 52 to the monitoring
30 unit, or processor, 25. The telephone jack provides a polarized connection for the 4-signal connector interface. An isolation op amp with a gain of one can provide an interface buffer in processor 25 between the sensor and the micro-controller

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operation. This interface can also protect the sensor from static discharge and misalignment of the connector (4 pins). The circuitry as a whole is typically a simple voltage divider, but a current driven op amp may provide a measurement of the total wetness of a variety of sensor configurations.

As described, one embodiment of the incontinence sensor assembly according to the invention is made with a thin polyester stock as the substrate. In general, any base material that is thin, flexible, easy to handle, inexpensive and stable to water can be used as the substrate for the sensor system of the invention. In an alternative embodiment, both sides of the sensor substrate layer are absorptive and provide for fluid access to the conductive circuit.

In general, an incontinence sensor assembly according to the invention can be used with any type of processor control box that will provide a notification mechanism (such as a CRT display, an audible alarm, a call button, a wireless page, a flashing light or a vibration) to either the user or caregiver, as is described herein. Connection to the control box processor can be by a direct connection or by any type of wireless connection. In the most general case, a microprocessor in the control box can process the information and route it anywhere via the internet or via wireless modem.

While the present invention has been described in conjunction with a preferred embodiment, one of ordinary skill, after reading the foregoing specification, will be able to effect various changes, substitutions of equivalents, and other alterations to the compositions and methods set forth herein. It is therefore intended that the protection granted by Letters Patent hereon be limited only by the definitions contained in the appended claims and equivalents thereof.

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CLAIMS

What is claimed is:

1. A body fluid sensor for remote volume reading comprising:
 - 5 a first layer for supporting a conductor pattern;
a conductor pattern on said first layer, said pattern having at least a first electrode of at least a given length and a second electrode of at least said given length, said first and second electrodes extending said given length in closely spaced
10 relationship to define a sensing length and being electrically isolated one from the other;
said pattern including conductive strips from said first and second electrodes to first and second connections for electrical contact external of said sensor;
 - 15 an apertured cover over said first layer and the conductor pattern thereon with plural apertures in said cover aligned with said sensing length at staggered intervals thereof;
a fluid absorbent skin over said cover whereby fluids applied to said skin migrate through one or more of the apertures
20 of said cover to provide an electrical bridge of a resistance characteristic of said fluid between said electrodes in the area of each aperture having said fluid migrated therethrough.
2. The sensor of claim 1 wherein said first layer is a dielectric
25 or insulating layer.
3. The sensor of either of claims 1 or 2 wherein said conductor pattern is a printed pattern.
- 30 4. The sensor of claim 3 wherein said printed pattern is an ink pattern.
5. The sensor of claim 4 wherein said ink is a carbon ink.

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6. The sensor of any of claims 1 to 5 wherein a plurality of separated sensing lengths are provided on said first layer.

5 7. The sensor of claim 6 wherein said plural separated sensing lengths have respective electrodes electrically connected together.

8. The sensor of claim 6 or 7 wherein said plural separated
10 sensing lengths are in an interdigitated relationship on said first layer.

9. The sensor of any of claims 1 to 8 wherein said fluid absorbent skin is a paper layer.

15
10. The sensor of any of claims 1 to 9 further including a third connection to one of said first and second electrodes via a conductive strip so as to provide a resistance between said third connection and one of said first and second connections
20 representative of a length of said sensor.

11. The sensor of claim 10 further including a forth connection and a resistive bridge between said fourth connection and one of said first, second and third connections of a resistance
25 predetermined to indicate a characteristic of said sensor.

12. The sensor of claim 11 wherein said characteristic includes an indication of one or more of sensor use and sensor configuration.

30
13. The sensor of claim 12 wherein said use includes bed or wheel chair use.

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14. The sensor of claim 12 or 13 wherein said configuration is substantially one dimensional or substantially two dimensional.

15. The sensor of any of claims 1 to 14 wherein said first layer
5 includes an apertured cover covered by a skin.

16. The sensor of claim 15 wherein said apertured cover is substantially nonconductive and has apertures aligned with one or more of the apertures of said first mentioned cover.
10

17. The sensor of any of claims 1 to 16 further including processing means for sensing a resistance between any of said connections.

18. The sensor of claim 17 wherein said processor applies a resistance of a predetermined value across said first and second electrodes.
15

19. The sensor of claim 18 wherein said predetermined value is substantially greater than the characteristic resistance of one or more electrical bridges.
20

20. A method of manufacturing a body fluid sensor for remote fluid volume reading comprising:
25 forming a first layer for supporting a conductor pattern;
forming a conductor pattern on said first layer, said pattern having at least a first electrode of at least a given length and a second electrode of at least said given length, said first and second electrodes extending said given length in closely spaced relationship to define a sensing length and being
30 electrically isolated one from the other;

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forming said pattern to include conductive strips from said first and second electrodes to first and second connections for electrical contact external of said sensor;

5 forming an apertured cover over said first layer and the conductor pattern thereon with plural apertures in said cover aligned with said sensing length at staggered intervals thereof;

forming a fluid absorbent skin over said cover whereby fluids applied to said skin migrate through one or more of the apertures of said cover to provide an electrical bridge of a
10 resistance characteristic of said fluid between said electrodes in the area of each aperture having said fluid migrated therethrough.

21. The method of claim 20 wherein said first layer is formed of a dielectric or insulating layer.
15

22. The method of either of claims 20 or 21 wherein said conductor pattern is formed by printing said pattern.

23. The sensor of claim 22 wherein said printing is of an ink
20 pattern.

24. The method of claim 23 wherein said ink is a carbon ink.

25. The method of any of claims 20 to 24 including the step of providing a plurality of separated sensing lengths on said first
25 layer.

26. The method of claim 25 including the step of electrically connecting said plural separated sensing lengths together.
30

27. The sensor of claim 25 or 26 including the step of forming said plural separated sensing lengths in an interdigitated relationship on said first layer.

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28. The method of any of claims 20 to 27 wherein said fluid absorbent skin is a paper layer.

5 29. The method of any of claims 20 to 28 further including the step of forming a third connection to one of said first and second electrodes via a conductive strip so as to provide a resistance between said third connection and one of said first and second connections representative of a length of said sensor.

10

30. The method of claim 29 further including the step of forming a forth connection and a resistive bridge between said fourth connection and one of said first, second and third connections of a resistance predetermined to indicate a characteristic of said
15 sensor.

31. The method of claim 30 further including the step of predetermining said characteristic to provide an indication of one or more of sensor use and sensor configuration.

20

32. The method of claim 31 wherein said use includes bed or wheelchair use.

25 33. The method of claim 31 or 32 including the step of providing said configuration as substantially one dimensional or substantially two dimensional.

30 34. The method of any of claims 20 to 33 including the step of forming said first layer to include an apertured cover covered by a skin.

35. The method of claim 34 including the step of forming said apertured cover to be substantially nonconductive and having

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apertures aligned with one or more of the apertures of said first mentioned cover.

36. The method of any of claims 20 to 35 further including the
5 step of providing processing means for sensing a resistance
between any of said connections.

37. The method of claim 36 including the step of applying a
resistance of a predetermined value across said first and second
10 electrodes.

38. The method of claim 37 including the step of forming said
predetermined value substantially greater than the characteristic
resistance of one or more electrical bridges.

15

39. An incontinence sensor comprising
a layer of a flexible substrate, said substrate being
impervious to moisture;
a circuit comprising a variable resistor laid down on a
20 surface of said substrate; and
an absorbent layer laid down over said circuit.

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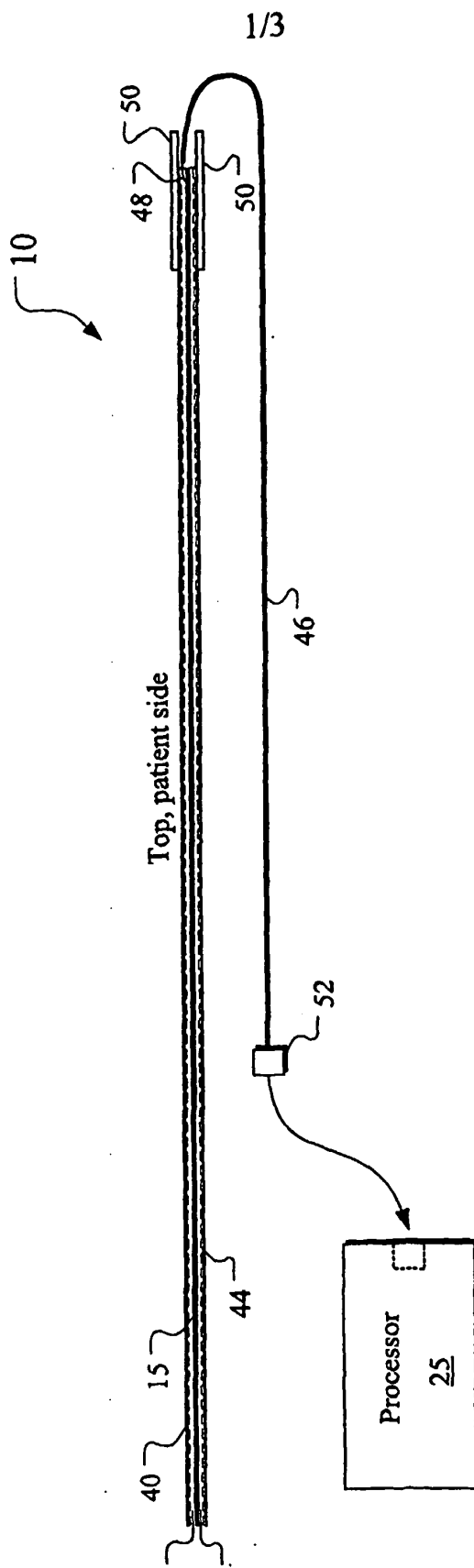


FIG. 1

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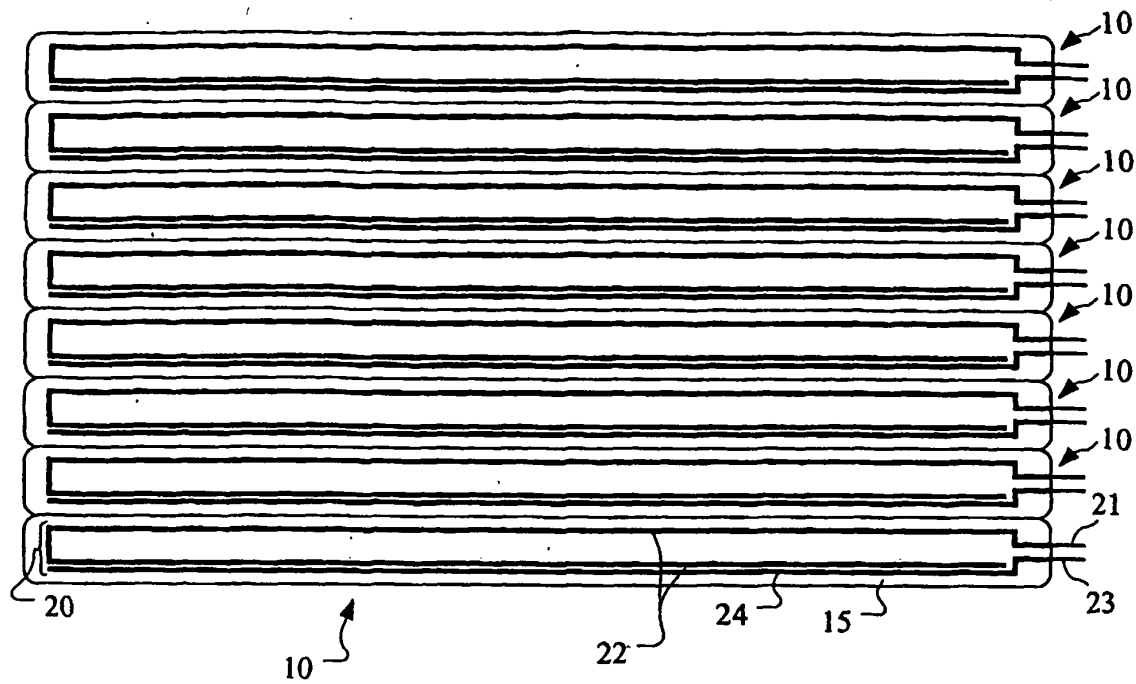


FIG. 2a

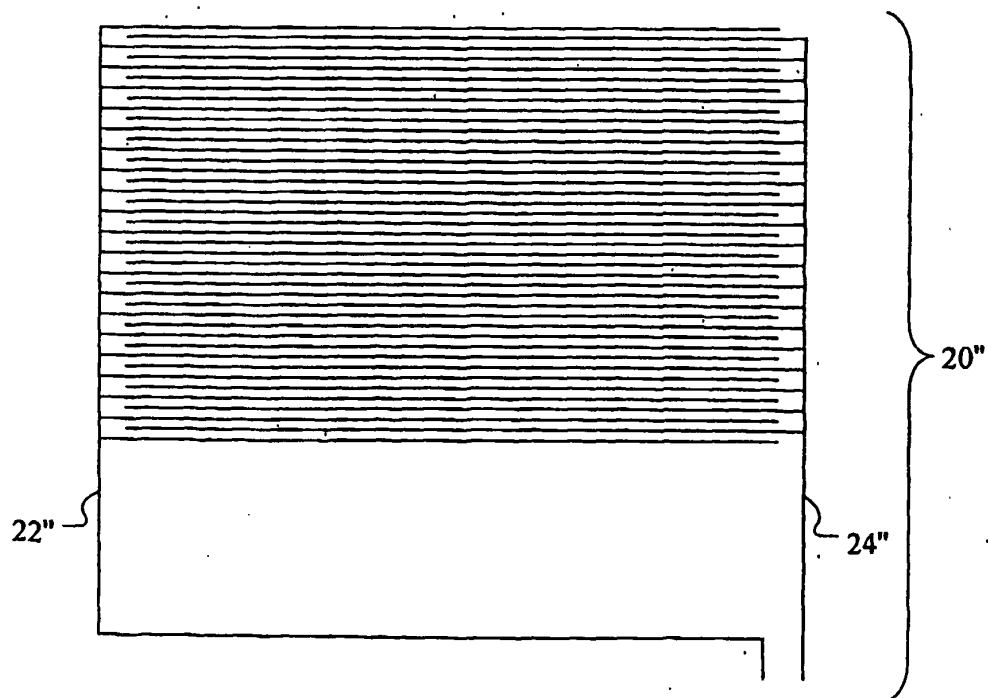


FIG. 2b

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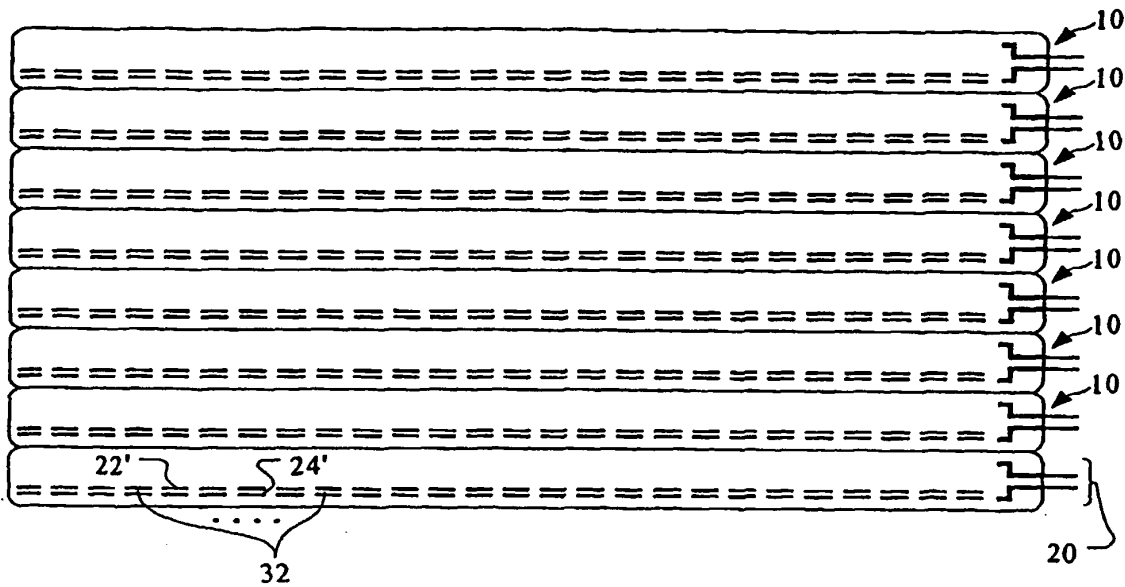


FIG. 3

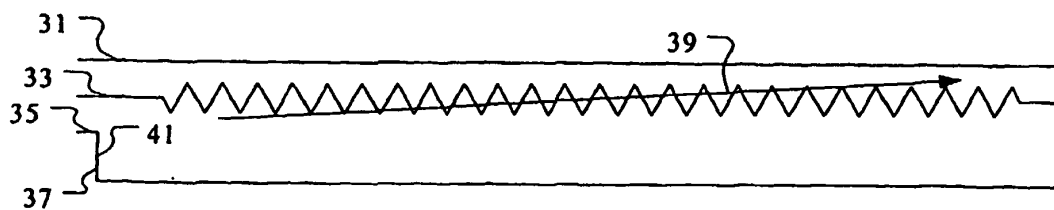


FIG. 4

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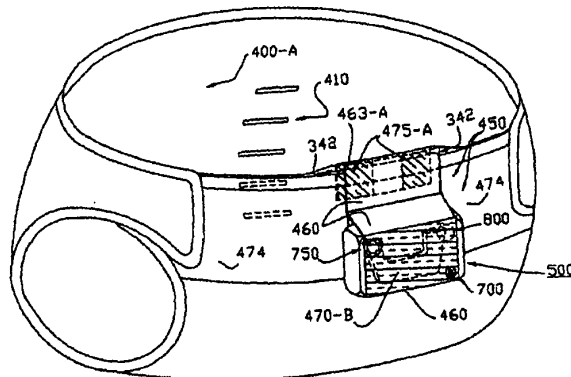
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(54) Title: ELIMINATION-ABSORBER MONITORING SYSTEM



(57) Abstract: An elimination-absorber monitoring system addresses diaper-monitoring problems (400) with a unique, low cost, multi-layer disposable sensor (100) structure that absorbs small volumes of urine, yet allows most urine volume to flow unimpeded through it, and into the diaper (400) below. When connected with a reusable, miniature monitor/indicator unit (500), the sensor (100) presents a clear and on-going change of measurement condition upon experiencing a rapid influx into the diaper (400) of a significant volume of urine, and/or upon a significant reduction in the available absorbency of the diaper's top surface (474). The sensor (100) additionally provides recessed, protected elements for similarly presenting a clear and on-going change in measurement condition upon experiencing the presence of fecal matter. Further provided is the monitor unit (500) employing narrow, widely-spaced, fast-time, fast transition-time pulses for conductivity measurement and alarm activation. The monitor (500) and sensor (100) are interconnected and attached to diaper (400) by particularly effective and unique means, and the monitor is equipped with a highly intuitive and convenient control interface, as well as improved assemblies for the transmission of audible and visual alarm indications. Also described is a convenient test-strip device which, when connected to the monitor/alarm unit of the system, can selectively simulate either a soiled or unsoiled elimination-absorber/sensor for test, caregiver-training or demonstration purposes.

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ELIMINATION-ABSORBER MONITORING SYSTEM

FIELD OF THE INVENTION

5 The present invention relates to systems and devices for monitoring the condition of a diaper, other undergarment, bedding or the like; particularly with regard to the clean or soiled status thereof, and specifically to a sensor and monitor/alarm assembly useful as an elimination-absorber monitoring system.

BACKGROUND INFORMATION

10 Inventors have long sought to provide a system of associated devices for effectively monitoring the condition of a diaper, other undergarment, bedding or the like. While the present invention provides an elimination-absorber monitoring system useful in each of these environments, a preferred embodiment is utilized in conjunction with a disposable diaper. Thus, for purposes of brevity in the present specification, the term "diaper" shall
15 indicate any of the above-described use environments, except where otherwise specifically stated or apparent from context.

The art is replete with examples of prior attempts to satisfy the need for an elimination-absorber monitoring system. Each has, for one reason or another, apparently failed to achieve significant implementation and consumer acceptance. Upon review, the prior systems appear either impractical, unsuitable to the use environment, unworkable
20 and/or uneconomical -- largely for one or more of the following reasons: failure to provide an appropriate sensor response or alarm criteria with respect to urine-soiling; inability to detect fecal matter, or to provide an appropriate sensor response or alarm criteria with respect to feces-soiling; lack of important user-oriented features; and unsuitability to cost-effective manufacturing.
25

Most previous systems have utilized the measurement of electrical conductivity between two spaced electrodes disposed somewhere on top of, within, or under the absorbent layers of a diaper, to detect the presence of liquid urine when it bridged some path between the electrodes. This approach is described in U.S. Pat. Nos. 3,460,123
30 (Bass), 4,356,818 (Macias), 4,800,370 (Vetecnik), 4,539,559 (Kelly), 4,768,023 (Xie), 5,036,859 (Brown), 5,264,830 and 5,392,032 (Kline), 4,205,672 (Dvorak), and 5,266,928 and 5,395,358 (Lu). These systems all depended on the relatively high conductivity of urine, as compared to the typically low conductivity of unsoiled, dry diaper materials. Several of these prior inventors clearly assumed that the key to a useful "diaper wetness" alarm (as
35 their objective was often termed) would be the detection of virtually any urine in a diaper. They also recognized that, depending on the sensor configuration, urine could miss the intended target. Thus, variations of this approach incorporated either distributed (e.g., screen-like) electrodes or various absorbent pads or modifications of a diaper to help collect, funnel or direct urine flow to bridge the sensing electrodes, e.g., U.S. Patent No. 4,356,818
40 (Macias). However, this focus on the detection of simple "wetness" resultant from urination -- as opposed to the far more useful determination that an elimination-absorber actually required changing (or at least inspection) -- failed to answer the real needs of caregivers

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and diaper-wearers. As with all the prior systems, seemingly little emphasis was placed on defining and obtaining truly user-responsive sensor performance. While this simple "wetness detection" focus may have appeared somewhat workable, as applied to certain cloth or early low-absorbency diapers, it did not adequately address the effects of widely differing flow-rates and volumes in various urination events and situations. Moreover, for reasons that shall be explained below, this approach was completely incompatible with the properties (and particularly the much greater capacity) of modern disposable diapers. Thus, previous systems based on simple "wetness detection" typically either failed to work consistently, or were prone to meaningless or premature alarm indications.

Some prior attempts took the view that a "soiled" diaper condition could be deduced by simply detecting the arrival of urine at the bottom (just inside the outer cover) of a diaper, i.e., that this would indicate when the diaper had reached its absorbent capacity. However, high-absorbency diapers are specifically designed to prevent urine from soaking to the outer cover, at least during the expected wearing time. Because urine permeates into and through a diaper with at least some time delay, additional urine will continue to collect after it first reaches a pair of sensing electrodes. If urine is detected only after soaking to the bottom of a diaper, the continued accumulation will tend to quickly spread along the inside of the cover, and quite likely leak out before the diaper can be changed. Thus, the determination of a fully saturated condition based on the sudden presence of urine at the bottom layers is not practically useful. Even completely non-electronic approaches to diaper monitoring, such as the "happy face" visual indicators incorporated into the outer cover of Fitti™ brand diapers, can similarly suffer from the limitations of over-simplified alarm criteria and inappropriate, inconsistent, or untimely sensor response. Also, such purely visual wetness-indicating devices, which are necessarily disposed directly on a diaper cover, have limited value for other reasons. Just as with traditional methods, they still require frequent and continual checking by a caregiver -- and the awkward removal of clothing layers worn over a diaper -- to permit viewing of the indicator. They thereby fail to provide a convenient, automatic, attention-getting signal that a diaper needs changing.

Still other inventors tried to "intercept" the flow of urine somewhere in the mid-layers of a diaper, but as will be appreciated by those skilled in the art, another problem results from the modern disposable diaper being such an aggressive absorber. No choice of conductivity-sensing path within such diapers (including midway through the absorbent layers) is likely to conveniently go from "dry" to fully "wet" at such time as to appropriately reflect a "needs to be changed" condition. In some such diapers, "super-absorbent" particles or polymer jells have been used to dramatically increase the liquid-holding capacity in a central core of the absorbent structure. These central absorbers are typically surrounded by conventional (e.g., cellulose based) absorbent wadding because the super-absorbers tend to react relatively slowly in absorbing liquid, as compared to the conventional materials. This means that the distribution of liquid through the diaper is highly non-uniform and it changes markedly after a urination event, as the super-absorber core gradually pulls liquid out of the conventional absorbent bulk. Also, with intermediate levels of moisture in any type of diaper (where the absorbent material is not yet completely saturated), urine can

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accumulate gradually or unevenly — often separated into discontinuous droplets or unpredictably scattered wet or merely damp regions. Thus, these regions may not happen to span a chosen path between electrodes so that the urine can be reliably detected. Moreover, the mere presence of relatively high conductivity (and hence the presence of liquid) along any given path through a diaper may not reflect a true "needs to be changed" condition (i.e., correlate with caregiver expectations or with traditional diaper inspection methods), particularly in the case of modern high-absorbency, disposable diapers. As explained above, none of the foregoing simple conductivity-based systems reflected a truly appropriate sensor response or "alarm criteria" with respect to urine-soiling of diapers. They typically responded either immediately or prematurely to the presence of trivial amounts of urine passing into a diaper; or alternatively, they responded either inconsistently, or not until after the diaper was soaked beyond its safe absorbent capacity — depending primarily on the choice of sensing location.

Other prior devices have measured AC-conductivity (or related electrical capacitance) across a bulk volume of diaper absorbent material, to achieve more appropriate alarm indications, e.g., U.S. Pat. Nos. 4,704,108 and 4,754,264 (Okada). These methods employed indirect determination of the average "moisture content" or "dampness" in some portion of the diaper absorber. This indirect determination was based on the presumed proportionality of average dampness to directly-measured capacitance or AC-conductivity. Proponents of this approach held that an accurate measurement exceeding a certain fixed threshold value would indicate a urine-soiled condition. They also held that such would be appropriate and sufficient to determine that a diaper needed changing. To be even partially correct, however, this assumption required that the portion of absorbent material actually measured be truly representative of the average dampness in the entire absorber volume. Also for meaningful measurements, that portion would have to be held in a constant shape and position, relative to the sensing means. Furthermore, selecting an appropriate fixed threshold value (that would remain valid with different sizes and applications of diapers) may not be possible. Thus, making sufficiently accurate and meaningful measurements (under all expected conditions) presented serious and unanswered practicality problems. These problems result from variations in measurable conductivity or capacitance due to many factors such as high humidity, perspiration, residual dampness from the washing of soiled skin, and the relative movement and random compression of the absorber as the wearer shifts position — all of which are likely to be experienced in the use environment.

In U.S. Pat. No. 5,469,145 (Johnson), the use of capacitive coupling of a sensing circuit (disposed on the outside of a diaper) to the material to be measured (inside the diaper) eliminated all direct connection between the monitoring device and the inside of a diaper. However, the described relatively high-impedance capacitor input to a monitor circuit would likely be particularly prone to external electrical noise and interference, as well as to significant capacitance variations due to unpredictable moisture distribution, the presence of other nearby conductive surfaces and physical movement — as the diaper wearer actively and continually shifts position. In short, all the previously described difficulties associated

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with other distributed dampness measurement approaches would tend to be worsened with the sensing elements moved farther away from the measurement volume. In addition, the use of continuous sinusoidal AC signals for sensing also typically entails greater energy consumption than does the use of DC conductivity methods. In prior systems this has
 5 required either the recharging or replacement of batteries, and thus complicated or precluded the use of a permanently sealed monitor unit.

Moreover, the prior systems were all ineffective for detecting the feces-soiling of diapers. Only a minuscule change in DC-conductivity or absorbent-bulk AC-conductivity (or capacitance) results from a small quantity of fecal matter on the surface of a diaper. This
 10 has rendered it typically undetectable by prior methods relative to much larger background changes produced by many of the above-described factors in the use environment. In general, the prior devices' collective inability to reliably detect feces stems from both the physical nature of the sensors and the electronic systems employed with them.

As described above, prior electronic systems have measured either DC or AC-conductivity or capacitance to detect urine. DC systems for accurately measuring liquid ionic conductivity typically require some "latching" means (such as circuits which detect an initial event and then remain "triggered"), because the applied electric field used for measurement causes dissociation of the very ions that enable electrical conduction, thus decreasing the measured conductivity over time. This effect poses only a minor problem
 20 when liquid urine directly bridges two closely spaced contacts, because the sudden initial increase in conductivity is substantial (due to the relatively high uric acid ionic concentration in urine) and this sudden increase can be easily differentiated from the baseline "dry diaper" condition. However, neither proportional bulk moisture content distributed in a diaper, nor the presence of feces, are suitable for direct DC-conductivity measurement. Particularly
 25 with feces, the ionic concentration is much lower than with direct liquid urine contact – and the water content, which allows the ions mobility, is often much lower in semi-solid waste. If a steady-state voltage is applied in an attempt to detect feces by inducing a DC current, the ionic dissociation effect results in rapid reduction in measured conductivity. With DC sensing of urine, a reference alarm threshold can be chosen such that the alarm condition
 30 will persist for a reasonable time – but probably not in all cases. This approach does not work at all with feces, however, because the initial conductivity is so low – and the decrease is so rapid – that after mere seconds, the conductivity falls below a practically measurable level. If a "latching" electronic detector is used to circumvent this problem – and is made sufficiently sensitive for detection of feces – this type of circuit may be easily triggered by
 35 momentary and insignificant conditions. Should this occur in actual use situations with a diaper monitoring system, caregiver intervention would likely be required to reset it. Because the true state of the diaper could not, in such cases, be reliably determined (without reverting to traditional diaper inspection), latching-type detectors are undesirable for use in elimination-absorber monitoring systems.

40 An additional problem is presented by the appropriate alarm criteria for feces-soiling. Since a diaper does not absorb feces and carry it away from direct contact with the skin (as it does with urine), and particularly given the irritation resultant from prolonged contact, feces

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must be detected virtually at the diaper surface -- and a feces-soiled diaper needs to be changed as quickly as is practical. Obviously, for feces detection purposes, the various prior AC bulk-dampness type of sensors were not useful, as their sensing elements focused on a bulk volume of a diaper, not on its surface. On the other hand, a sensor structure involving exposed electrodes placed on the top surface of a diaper, while not only disconcerting to a caregiver, would prematurely respond to the presence of any urine. Such arrangement would also greatly increase the likelihood of false alarms resulting from bridging of the electrodes through either AC-coupling, or direct contact with skin, particularly if damp. As discussed above, feces are relatively very low in conductivity, and are thus difficult for such a system to reliably detect in the use environment. The overall elimination-absorber feces-detection problem is even more difficult, because a truly practical system must effectively combine the determination of both feces and urine-soiling of diapers. Clearly, no prior system has successfully done so.

The absence of any widely marketed consumer product for elimination-absorber monitoring further highlights the unsuitability of prior inventors' attempts. Today's parents and caregivers are still embarrassed by sniffing our kids and pulling their pants down in public to see whether they need to be changed. Thus, the desire remains for a truly effective, economic, safe, reliable, convenient, and energy efficient system for use with infants and other individuals dependent on a caregiver. These and other objectives, as will become apparent from the following specification and drawings, are satisfied by the present invention.

SUMMARY OF THE INVENTION

A sensor, for use with an elimination-absorber monitoring system, has sensing means and a flow-baffling layer disposed to preclude direct flow of a liquid to be sensed onto the sensing means. The sensor can also have a first liquid-permeable flow-conducting layer disposed adjacent the flow-baffling layer, opposite the sensing means, to collect and conduct a liquid to be sensed across said flow-baffling layer. A second liquid-permeable flow-conducting layer can be disposed adjacent the flow-baffling layer, opposite the first flow-conducting layer, to conduct liquid from the first flow-conducting layer, around the flow-baffling layer and toward the sensing means. In a preferred embodiment, the first and second flow conducting layers extend beyond the flow-baffling layer and have a portion disposed adjacent and in fluid communication with each other. In a further preferred embodiment, the first flow conducting layer extends beyond the second flow conducting layer and has a portion disposed (or disposable) adjacent to and in fluid communication with an elimination-absorber. In another preferred embodiment, the sensor has a second relatively liquid-impermeable layer disposed opposite the flow-baffling layer, with respect to the sensing means and the second flow-conducting layer, to form a capillary channel within the sensing means. The relatively liquid-impermeable layer is sufficiently wide to preclude direct flow between the sensing means and the elimination-absorber.

In another embodiment, the sensor has a first series of openings through and disposed toward the outer edges of the flow-baffling layer to conduct liquid from the first

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flow-conducting layer, through the flow-baffling layer and to the second flow-conducting layer, and a second series of openings through the flow-baffling layer, disposed between the first series of openings and the outer edges of the flow-baffling layer to conduct liquid from the first flow-conducting layer, through the flow-baffling layer, to the elimination-absorber. In this embodiment, the second flow-conducting layer is sufficiently wide to communicate with the first flow-conducting layer through the first series of openings, but not through the second series of openings. It is disposed between the flow-baffling layer and the sensing means.

In another embodiment of the sensor the second flow-conducting layer is preferably selected from a material that is less absorbent than a dry elimination-absorber, but more absorbent than an elimination-absorber sufficiently wetted to require replacement. The second flow-conducting layer is configured in size and materials to delay the conduct of the liquid from the first conducting-layer to the sensing means until the elimination-absorber is sufficiently wetted to require replacement.

In yet another embodiment of a sensor for use with an elimination-absorber monitoring system, the sensor has a flow-baffling layer disposed to preclude direct flow of a liquid to be sensed onto sensing means disposed beneath the flow-baffling layer, and a series of openings through the flow-baffling layer, the openings being of sufficient size, shape and thickness to permit the passage of a semi-solid or solid material to be detected (such as feces) to contact the sensing means, while deterring contact between the sensing means and the skin of a wearer of the elimination-absorber. It is preferred that the openings be disposed posterior to the sensor portion most likely to be directly impacted by a drop or stream of urine. It is also preferred that to provide a liquid-permeable flow-conducting layer disposed adjacent the flow-baffling layer, opposite the sensing means, the flow-conducting layer be sufficiently absorbent to retain and thereby prevent small volumes of liquid or condensation from penetrating the openings and being detected by the sensing means. The flow-baffling layer is provided with a series of openings disposed adjacent to and in communication with the openings through the flow-baffling layer. The flow-baffling layer is preferably relatively hydrophobic as compared to the flow-conducting (or absorbent) layer, even when the absorbent material becomes saturated, and the flow-conducting layer can be bounded by the liquid-impermeable layer to direct the flow of liquid away from the openings. It is also preferred that a cover layer be disposed adjacent to the flow-baffling layer opposite the sensing means (or in the embodiment including a flow-conducting layer, adjacent the flow-conducting layer's surface farthest from the sensing means), the cover layer having nominally closed slits/flaps covering the openings. These slits/flaps are resistant to passage of urine but displaceable by contact with feces to permit the passage of feces into the openings.

The sensor of the present invention can be incorporated as part of a disposable diaper or adapted for application to an elimination-absorber, in which embodiment there are provided means for affixing the sensor to the elimination-absorber, and an optional cover layer for separating the first flow-conducting layer from the skin of a wearer of the elimination-absorber.

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In still another embodiment of the invention, there is provided a monitor/alarm unit retainer for use with an elimination-absorber monitoring system, the retainer having an interlocking protrusion and receiving portion respectively disposed on either an elimination-absorber/sensor or an elimination-absorber monitor, the elimination-absorber/sensor having an elastic or semi-elastic flap adapted to be stretched over the monitor/alarm unit and releasably adhered to the elimination-absorber. In a preferred embodiment the flap is of a sufficient size to be stretched over the monitor/alarm unit and over the waistband of the elimination-absorber to be adhered both to the front of the diaper and also to a diaper portion inside the waistband. The retainer is preferably employed with the releasable circuit electrical connector of the invention, which includes a flexible-tab portion and a tab-receiving portion. The tab portion has two or more conductive members disposed on a resilient support. The tab-receiving portion has two or more protruding contacts arranged to engage the conductive members, lateral surfaces for guiding and positioning the tab, and has means to deform the resilient support into a wave-like shape thereby retaining the tab portion while maintaining its orientation and pressure against the contacts to ensure continuous electrical connection of the conductive members with the contacts. This connector has applicability in widely varying environments and systems, and is not intended to be limited to application with the elimination-monitoring system of the invention.

Also provided is an elimination-absorber monitoring system kit including one or more of any of the sensors of the invention with a monitor/alarm unit, and preferably including a test strip for use in confirming proper function of the system. The monitor/alarm unit preferably includes a power source, an alarm means, an interlocking protruding or receiving portion corresponding with the reciprocal portion on the monitor/alarm unit retainer, a releasable sensor connector (as described above), and electronic circuitry employing relatively narrow, relatively low duty-cycle pulses to measure conductivity or capacitance between a pair of spaced conductors or semiconductors that are disposed within or that span an appropriate measurement path relative to the elimination-absorber to be monitored and actuates the alarm means when the elimination-absorber probably requires replacement. The monitor/alarm unit forms a separate aspect of the present invention. It is preferably provided within a waterproof case enclosing the power source, the alarm means and the electronic circuitry. The releasable sensor connector is preferably fabricated as part of the case. The case has control surfaces with access for the alarm means and control means, the access being sealed by a thin, at least partially flexible membrane.

In another aspect of the invention there is provided visible alarm means including an electro-optical source disposed in a through-opening that is sealed by a relatively thin, substantially optically-permeable covering. In a preferred aspect, disposed above the visible alarm means covering is a removable or repositionable, relatively thin, light-transmissive, protective or retaining covering layer, flap or pocket of material above. The flap significantly protects, retains and positions the monitor/ alarm unit and acts as a rear-projection screen for the electro-optical source, dispersing or de-focusing the relatively narrow light beam from an electro-optical source into a significantly wider beam or viewing angle than that of the source.

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In still another aspect, audible alarm means are located behind a shallow recess in the case disposed behind an audibly transmissive, relatively thin flexible membrane with a sound permeable, structurally supportive, relatively rigid, perforated bottom. The recess allows the membrane to vibrate freely in response to acoustic pressure waves from an electro-acoustic transducer disposed behind the recess but which limits the maximum deflection of the membrane to within its elastic limit thereby protecting the membrane from mechanical damage without excessively attenuating the sound transmission from the transducer during intended operation.

Control means are provided, disposed through a surface of the case. The control means both changes and indicates the alarm or indicative function selected for the system's operation in response to repeated actuation, where the indication is by means of the visible or audible alarm to emit a representative signal. The control means preferably provides such indication only upon proper connection of an elimination-absorber sensor through the releasable sensor connector.

Also described is a convenient test-strip device which, when connected to the monitor/alarm unit of the system, can selectively simulate either a soiled or unsoiled elimination-absorber/sensor for test, caregiver-training or demonstration purposes.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a top plan view showing the two main elimination-absorber monitoring system components, i.e., a disposable sensor and a reusable monitor/alarm unit. For purely illustrative purposes, these components are shown arranged in linear fashion atop the sensor's protective packaging layer as employed in a preferred, disposable add-on embodiment of the invention. Although a sensor is shown with the monitor unit already interconnected, these components would normally not be combined prior to installation of the sensor on a diaper. Sensors are intended to be pre-installed on diapers, after which the monitor unit is attached when a diaper is needed.

Fig. 2A is a perspective illustration of a preferred embodiment of the system with the sensor installed as an add-on to a disposable diaper. The sensor's strippable top protective layer is shown to the right, as if just removed from the area of the sensor that is folded over the top front of the diaper. Also shown is the reusable monitor unit, as if poised for connection and attachment to the sensor-equipped diaper.

Fig. 2B is a perspective illustration of the system as shown in **Fig. 2A**, where the monitor unit has been connected to the sensor and secured to the front of the diaper, ready for use.

Fig. 3 is a top plan view, showing the various superposed layers of the sensor, including its connection and retention means. The sensor is shown disposed linearly, as if laid out on a flat surface, with both top and bottom protective layers removed. The horizontal scale of the figure and the dashed fold line correspond to **Fig. 1.** and to **Fig. 4.** In **Fig. 3,** as well as in most following views of the sensor and its components (but not, of course, in the cross-sectional views), the relative position of the sensor fold line is shown for reference.

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Fig. 3A is a close-up cross-sectional view in elevation taken along line A-A in Fig. 3 (but magnified in scale), showing an embodiment of the feces-responsive structural features of a sensor.

5 **Fig. 3B** is a close-up cross-sectional view in elevation taken along line B-B in Fig. 3 (but magnified in scale), showing an embodiment of the urine-responsive structural features of a sensor.

Fig. 3C is a close-up cross-sectional view in elevation taken along line C-C in Fig. 3 (but magnified in scale), showing an embodiment of the portion of a sensor that is disposed just outside and on the top front of a diaper when installed for use. For clarity, the sensor's monitor unit locating block is not shown.

Fig. 3D is a close-up cross-sectional view in elevation showing an alternative embodiment having a narrower flow-baffling layer without peripheral openings therethrough, taken at a point similar to that illustrated in Fig. 3B (also magnified in scale).

15 **Fig. 4** is a side (edge) view in elevation of a complete, preferred add-on embodiment sensor showing all layers. The thickness and vertical separation of each layer is exaggerated, to clarify its relative position and length. The horizontal scale of Fig. 4 and the dashed fold line both correspond to Fig. 1. and to Fig. 3.

Fig. 5A is a close-up "exploded-view" perspective illustration of the monitor connecting/locating/retaining portion of the elimination-absorber sensor. (The removable bottom protective layer is not shown.)

20 **Fig. 5B** is a close-up side view of a preferred embodiment of the reusable electronic monitor unit, shown mated to the monitor connecting/locating/retaining portion of the sensor. For clarity, the diaper itself and the in-diaper portion of the sensor beyond the fold line (to the left) are not shown. Hidden (dashed) lines indicate the tab connector portion of the sensor as inserted into the connecting portion of the monitor unit, and how a preferred type of locating block of the sensor is captured under the monitor case. Also shown is the sensor flap portion wrapped around and over the monitor to retain it on the top front of the diaper.

Fig. 6 is a top plan view of the removable bottom protective layer.

30 **Fig. 7** is a top plan view of the lower connecting/attaching layer of the coupling and retention portion of the sensor.

Fig. 8 is a top plan view of the monitor unit retaining flap layer of the sensor.

Fig. 9 is a top plan view of the monitor unit locating block of the sensor.

Fig. 10 is a top plan view of the reinforcing connector tab of the sensor.

35 **Fig. 11** is a top plan view of the lower impermeable layer of the in-diaper portion of the sensor.

Fig. 12 is a top plan view of elements of the sensor's electrically conductive layer.

Fig. 13 is a top plan view of the lower sensor absorbent layer.

Fig. 14 is a top plan view of the sensor substrate (upper impermeable) layer.

Fig. 15 is a top plan view of the sensor upper absorbent layer.

40 **Fig. 16** is a top plan view of the sensor cover layer.

Fig. 17 is a top plan view of the sensor strippable top protective layer.

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Fig. 18A is a front (faceplate) view of the monitor/alarm unit. (This view corresponds to the "top plan view" of the unit as it is shown positioned in Fig. 1.)

Fig. 18B is a top edge view of the monitor/alarm unit, showing the opening of the sensor tab receiving portion.

5 **Fig. 18C** is a back view of the monitor/alarm unit.

Fig. 18D is a bottom edge view of the monitor/alarm unit.

Fig. 19A is a close-up (magnified scale) back view of the contact spring clip/plate of the monitor/alarm unit.

10 **Fig. 19B** is a close-up (magnified scale) top edge view of the contact spring clip/plate of the monitor/alarm unit.

Fig. 20 is a close-up cross-sectional view in elevation taken along line 20-20 in Fig. 1 (but magnified in scale), showing an embodiment of the releasable electronic coupling and retention portion of the sensor, attached to the monitor/alarm unit. This view also shows the flexible, elastic tab-like male connector portion of the sensor, with the conductive members on its upper surface, attached to the monitor/alarm unit. The tab-like sensor portion is shown as deformed between the monitor unit contact-pins, and the prongs of the spring clip/plate.

Fig. 21A is a close-up perspective illustration of an alternate embodiment re-usable electronic monitor unit and a segment of the tab-like connector portion of an alternate embodiment disposable sensor, shown entering the receiving portion of the monitor unit.

20 **Fig. 21B** is a close-up perspective illustration of another alternative embodiment of the monitor unit and the connector tab portion of a corresponding sensor embodiment, shown entering the monitor unit's receiving portion parallel to an edge of the monitor unit, instead of parallel to the back of the unit as in Fig. 21A.

Fig. 22A is a perspective illustration of an embodiment of the system with the sensor incorporated directly into a disposable diaper. The monitor-retaining flap portion of the sensor is disposed on the front of the diaper, much like in the add-on embodiment illustrated in Fig. 2A and Fig. 2B. In Fig. 22A, however, the inner diaper surface is modified to replace the cover layer of the add-on embodiment, and the other layers of the in-diaper portion of the sensor are integrated under this surface. The tab connector portion and monitor-retaining flap portion of the sensor protrude from between the inner and outer diaper covers, over or near the diaper's top front edge.

Fig. 22B is a perspective illustration of an alternate embodiment of the monitoring system with the sensor incorporated directly into a disposable diaper, where the sensor's monitor-retaining flap does not first pass under the back of the monitor unit before wrapping over its front (as in Fig. 22A), but instead wraps directly downward over the monitor, to be adhered or otherwise attached to the front of the diaper/sensor below the monitor.

40 **Fig. 22C** is a perspective illustration of an alternate embodiment of the sensor, also incorporated directly into a disposable diaper similar to that of Fig. 22B, but where the tab-like connecting portion of the sensor is designed to enter the monitor unit from the opposite (bottom) end. For use with this embodiment, the monitor unit's receiving portion is located on the bottom edge, rather than as in Fig. 22B.

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Fig. 22D is a perspective illustration of another alternate embodiment of the sensor, also incorporated directly into a disposable diaper similar to that of Fig. 22C, but where the tab-like connecting portion is designed to enter the monitor unit's receiving portion parallel to an edge of the monitor unit (as shown in Fig. 21B) instead of parallel to the bottom of the unit (as shown in Fig. 21A).

Fig. 22E is a perspective illustration of a preferred embodiment of the sensor as directly incorporated into a disposable diaper, similar to that of Fig. 22A, but where the flap portion of the sensor is disposed on the front of the diaper completely separate from the sensor portion inside the diaper. Also, instead of employing the locating block as shown entrapped under the monitor in Fig. 22B, slot-like openings in the flap portion are provided to receive mating ridges on the back surface of the monitor unit for locating purposes. The tab-like connector portion protrudes from the in-diaper portion at or near the top edge of the diaper.

Fig. 22F is a perspective illustration of an alternate preferred embodiment of the sensor as directly incorporated into a disposable diaper, showing an alternative monitor/alarm locating block and extended securing flap having separated adhesive areas.

Fig. 23 is a schematic block diagram of a discrete logic circuit employed in the monitor/alarm unit.

Fig. 24A is a schematic block diagram of a microcontroller-based circuit embodiment alternatively employed in the monitor/alarm unit.

Fig. 24B is a schematic block diagram of a microcontroller-based circuit embodiment alternatively employed in the monitor/alarm unit.

Fig. 24C is a schematic block diagram of a microcontroller-based circuit embodiment alternatively employed in the monitor/alarm unit.

Fig. 24D is a schematic block diagram of a microcontroller-based circuit embodiment alternatively employed in the monitor/alarm unit.

Fig. 25 is a flowchart of the firmware employed in conjunction with a microcontroller-based embodiment of the monitor/alarm unit (as in Fig. 24A).

Fig. 26A depicts a close-up perspective view of an alternate version of the connector embodiment shown in Fig. 20, where a short (sectioned) piece of the flexible, tab-like connector portion of the sensor is shown deformed between the monitor unit contact-pins (on one side) and fixed ramping projections (on the opposite side), instead of by the spring clip/plate used in Fig. 20.

Fig. 26B depicts a perspective view of another alternate embodiment of the flexible-tab connector means used in the monitor unit and the sensor; where the short (sectioned) flexible, tab-like connector portion of the sensor is shown deformed from both sides between alternating fixed ramping projections of the receiving connector portion, and where any number of projections can be employed, and where any of them can be conductive.

Fig. 27 is a close-up cross-section view of the high viewing-angle visible display means of the monitor unit.

Fig. 28 is a close-up cross-section view of the sealed audible alarm means of the monitor unit.

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Fig. 29A is an “exploded-view” perspective illustration of a manufacturing assembly method employed with an embodiment of the monitor/alarm unit, as is shown in Fig. 21A.

5 Fig. 29B is an “exploded-view” perspective illustration of an alternate manufacturing assembly method employed with another embodiment of the monitor/alarm unit, as is shown in Fig. 21B.

Fig. 30A is a perspective illustration of one side of a sensor-simulating test strip device for use with the monitor/alarm unit.

10 Fig. 30B is a perspective illustration of the opposite side (relative to Fig. 30A) of a sensor-simulating test strip device for use with the monitor/alarm unit.

Reference Numbers Used in the Drawings and Detailed Description

<u>No.</u>	<u>Description</u>
100	Disposable sensor for elimination-absorber monitoring.
102	Top of sensor 100.
104	Bottom of sensor 100.
105	Side edges of sensor 100.
106	Distal end of sensor 100.
108	Proximal end of sensor 100.
110	Protective layer (covering bottom prior to installation) of sensor 100.
112	Strippable portion of protective layer 110.
114	Wrapping portion of 110.
116	Releasable adhesive fastening tape for wrapping portion 114.
150	Lower impermeable layer of sensor 100.
152	Center core of layer 150.
154	Upper adhesive of layer 150.
156	Lower adhesive of layer 150.
160	Channel between elements 202 and 204 of layer 200.
162	Optionally narrowed front portion of layer 150.
164	Front (proximal) end of layer 150.
166	Tab stiffener of assembly 170 of sensor 100.
170	Male connector tab assembly portion of sensor 100.
200	Electrically conductive elements layer of sensor 100.
202	First electrically conductive member of layer 200.
204	Second electrically conductive member of layer 200.
206	Outer edges of elements 202 and 204.
208	Inner edges of elements 202 and 204.
250	Lower porous/absorbent layer of sensor 100.
252	Elongated feces-detection openings in layer 250.
254	Distal end of absorbent layer 250.
256	Outer edge of absorbent layer 250.

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- 258 Portion of layer 250, which contacts layer 350.
- 259 Portion of 250, corresponding to 258, which contacts elimination-absorber.
- 260 Second portion of layer 250, which contacts elimination-absorber.
- 300 Upper impermeable layer of sensor 100.
- 302 Center core of impermeable layer 300.
- 304 Upper adhesive of layer 300.
- 306 Lower adhesive of layer 300.
- 308 Outer edges of layer 300.
- 309 Portion of lower adhesive 306 alternatively fixing layer 400.
- 310 First (outer or "spillway") series of openings in layer 300.
- 312 Front-most edges of openings 310.
- 314 Rear-most edges of openings 310.
- 316 Outermost edges of openings 310.
- 318 Innermost edges of openings 310.
- 320 Second (inner or "flow-splitting") series of openings in layer 300.
- 322 Outermost edges of openings 320.
- 324 Innermost edges of openings 320.
- 330 Elongated feces-detection openings in layer 300.
- 332 Gap through layer 300, separating absorbent layer 250 from 350.
- 340 Proximal end of layer 300.
- 342 Fold line of sensor (where it folds over top front edge of diaper).
- 344 Optional opening through layer(s) 300/460 for passage of tab assembly 170.
- 350 Upper porous/absorbent layer of sensor 100.
- 352 Elongated feces-detection openings in layer 350.
- 354 Outer edges of layer 350.
- 356 Portion of layer 350, which contacts elimination-absorber at 400-B.
- 358 Portion of layer 350, which contacts layer 250.
- 400 Cover layer of sensor 100 (contacts the skin of a diaper wearer).
- 400-A Inner (skin-contacting) modified diaper lining of incorporated sensor 100.
- 400-B Bulk absorbent portion of diaper having incorporated sensor 100.
- 402 Top surface of layer 400.
- 404 Bottom surface of layer 400.
- 406 Outer side edges of layer 400.
- 410 Elongated feces-detection openings in layer 400.
- 412 Line about which layer 400 is folded.
- 414 Line to which layer 400 is folded.
- 416 Side edge portions of cover 400 that are affixed to layer 300.
- 418 Floating soft edge of sensor 100 (layer 350 covered by layer 400).
- 450 Releasable electronic coupling and retention portion of sensor 100.
- 452 Connecting and attaching layer of portion 450.
- 453 Center core of connecting/attaching layer 452.
- 454 Top adhesive means of layer 452.

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- 455 Strippable top protective layer of sensor 100.
- 456 Bottom adhesive means of layer 452.
- 460 Monitor/alarm retaining flap of sensor 100.
- 462 Most proximal end of flap 460.
- 463 Pull-tab portion near end 462 of flap 460.
- 463-A Extended length embodiment of pull-tab portion near end 462 of flap 460.
- 470 Monitor/alarm locating block of sensor 100.
- 470-A Alternative monitor/alarm locating features of sensor 100.
- 470-B Alternative monitor/alarm locating block of sensor 100.
- 472 Notch in locating block 470.
- 474 Top front diaper surface where monitor 500 is retained/connected to sensor.
- 475 Alternative adhesive/adhesion areas for securing flap 460.
- 475-A Alternative, separated adhesive areas for securing flap 460.
- 500 Monitor/alarm unit.
- 510 Protective case of monitor/alarm unit 500.
- 512 Front portion of case 510.
- 514 Back portion of case 510.
- 516 Surface feature of case 510, emphasizing location of receiving portion 600.
- 517 Faceplate overlay on 512.
- 518 Balloon or other graphic symbol on faceplate 517 highlighting assembly 750.
- 520 Mating feature on back of 500 to engage locating block 470.
- 530 Top (edge) of case 510 (relative to position on the front of a diaper).
- 532 Bottom (edge) of case 510 (relative to position on the front of a diaper).
- 534 Left side of case 510 (as viewed from front or faceplate side).
- 536 Right side of case 510.
- 540 Acoustically transmissive opening(s) through case 510.
- 600 Sensor-connector receiving portion in the lower case half 514 of monitor 500.
- 605 Pressure-plate of alternative connector means in monitor unit 500.
- 606 Lead-in lip of pressure-plate 605 or recess 600.
- 610 Spring clip/plate of monitor unit 500.
- 610-A Alternative embodiment of 610.
- 612 First (e.g., plate-like outboard) prong of 610.
- 614 Second (e.g., center active spring clip) prong of 610.
- 616 Third (e.g., plate-like outboard) prong of 610.
- 617 Dovetail slots or other retention means.
- 618 Attachment means of clip/plate 610 to case 510.
- 619 Smooth rounded tip of prong 614 of clip/plate 610.
- 620 First contact pin of monitor unit 500.
- 621 First contact-pin socket of circuit board assembly 910.
- 621A Alternative first contact-pin pressure spring of circuit board assembly 910.
- 622 Second (center) contact pin of monitor unit 500.

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- 623 Second (center) contact-pin socket of circuit board assembly 910 .
- 623-A Alternative second contact-pin pressure spring of circuit board assembly 910.
- 624 Third contact pin of monitor unit 500.
- 625 Third contact-pin socket of circuit board assembly 910.
- 625-A Alternative third contact-pin pressure spring of circuit board assembly 910.
- 630 First contact pin of an alternate connector embodiment of monitor 500.
- 632 Second contact pin of an alternate connector embodiment of monitor 500.
- 634 Third contact pin of an alternate connector embodiment of monitor 500.
- 636 First opposed ramping protrusion of an alternate connector embodiment.
- 638 Second opposed ramping protrusion of an alternate connector embodiment.
- 700 Mode change assembly of monitor unit 500.
- 702 Dot or other graphic symbol indicating location of mode change assembly 700.
- 705 Hole through front case portion 512 for flush button of mode-change switch S1.
- 750 Visible signal transmission assembly of monitor unit 500.
- 755 Hole in face surface 516 of monitor 500 for visual signal transmission.
- 760 Chamfered edge of hole 755.
- 800 Audible signal assembly of monitor unit 500.
- 810 / BPR Electro-acoustic transducer of monitor unit 500 (also referred to as "BPR").
- 820 Acoustic wave propagation hole in transducer 810.
- 830 Shallow recess behind overlay faceplate membrane 517 in case 510.
- 900 Electronic circuitry employed in monitor/alarm 500.
- 905 Electronics printed circuit board of monitor unit 500.
- 910 Electronic circuit board assembly of monitor unit 500.
- 950 Diaper-simulating test-strip device for use with monitor 500.
- 960 Tab (substrate) of test strip device.
- 961 One side of system test strip device.
- 962 Opposite side (to 961) of system test strip device.
- 964 First area of conductive coating.
- 965 Second area of conductive coating.
- 966 Gap between conductive coating elements 964 and 965.
- 967 Area of conductive coating on side 962.
- 968 Chip resistor or other reference-valued device.
- 971 Indicative marking on side 961.
- 972 Indicative marking on side 962.
- 974 Hole or opening through 960.

NOTE: Other reference designators that appear only in the electronic schematic diagrams of **Fig. 23, Fig. 24A, Fig. 24B, Fig. 24C and Fig. 24D**, and in the text descriptions referencing those diagrams, are not listed above.

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DETAILED DESCRIPTION OF THE INVENTION

The present invention provides an elimination-absorber monitoring system having appropriate "alarm criteria" and detection methods to reliably establish that:

- 5 • a significant volume of urine has been rapidly discharged into a diaper, and/or,
- a diaper's remaining ability to absorb has been significantly reduced, and/or
- any feces has been deposited into a diaper.

10 The above conditions are defined and automatically detected so as to appropriately correlate with traditional perceptions of when a modern, high absorbency diaper should probably be changed (or at least ought to be inspected) collectively, for purposes of the present specification and claims, referred to as diaper "needs changing" or "needs to be changed." This response not only reflects the criteria of conventional checking, but it leads to diaper-changing at similar intervals.

15 Other requirements, identified and provided in the present invention for a disposable elimination-absorber monitoring sensor, pertain to its "feel", appearance and cost. The sensor is comfortable for the wearer, whether incorporated into a diaper or applied to its inner surface before use. It is soft, flexibly compliant and pleasing in appearance. From a cost standpoint, the materials are particularly economical and the sensor design is specifically oriented toward high-speed manufacturing processes such as continuous-strip based assembly methods.

20 In addition to providing a sensor system that consistently determines "diaper needs changing" conditions (with respect to both urine and feces soiling) in a manner responsive to the needs of both caregiver and wearer, the present invention additionally addresses certain practical problems with the prior approaches and critical needs that have remained

25 unanswered. The monitor unit produces a relatively pleasant audible alarm that can be heard from a reasonable distance over typical background noise and is compatible with common remote audio baby monitors. Audible alarms, however, are not desirable for night and nap use (or in certain public situations), so an alternative (e.g., visible) alarm that is designed to not disturb a sleeping infant or surrounding people is also provided. The visible

30 alarm is bright enough to be readily seen outdoors in daylight, or through one or more layers of clothing, and over wide viewing angles. Moreover, a caregiver can easily switch the monitor unit between alarm modes, and can do so with one hand, even through the wearer's clothing without needing to remove it. Re-usable monitor units for elimination-absorber monitoring systems will inevitably become exposed to moisture and, when soiled, require

35 cleaning. They are also likely to occasionally be dropped onto hard surfaces while being routinely handled. Thus, a compact, rugged, waterproof case is needed to house the monitor unit circuitry, switching means, and visible and audible alarms and to provide physical and electrical connection to a diaper and sensor. A fully sealed case potentially limits or altogether precludes access for battery recharging or replacement, however,

40 thereby complicating the power requirements for such a device. Therefore, the monitor unit's energy use must be sufficiently miserly for the complete system to be powered throughout its expected lifetime using a single, pre-installed battery. Additionally, a sealed

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monitor case can also inhibit audible and visual alarm signal transmission as well as complicating the reliable and convenient interconnection of the monitor unit with a disposable sensor. Thus, the system employs innovative means to effectively overcome these problems. The monitor unit attaches to, and can be removed from, the disposable sensor and diaper quickly and easily. It remains securely positioned and electrically connected while in use. A self-test indication of proper operation is automatically given when the system is activated (by means of simply attaching it to a disposable sensor/diaper). This self-test indication also confirms the mode (audible or visible) to which the monitor is set.

The System

As illustrated in Fig. 1, a preferred embodiment of the elimination-absorber monitoring system includes a releaseably-interconnected, disposable sensor 100 and a reusable monitor/alarm unit 500. The system is suitable for use with various diapers (reusable-cloth and disposable), undergarments, bedding and the like. A preferred use, i.e., with the sensor provided as an add-on product to be applied to disposable diapers (illustrated in Fig. 1, Fig. 2A and Fig. 2B), is the primary basis for the invention description. Modifications necessary to adapt the system or its components for use in other environments are also described below. For example, Fig. 22A depicts the sensor, pre-incorporated as part of a disposable diaper. In such an incorporated embodiment, a removable bottom protective layer 110 of the add-on unit shown in Fig. 1, is not necessary. Also, a top cover layer 400 and a top absorbent layer 350 (underneath layer 400) of the add-on unit can be replaced, respectively, by the diaper inner surface 400-A (shown in Fig. 22A) and an underlying portion of the diaper's absorbent layer(s). As will be described, the novel underlying operative principles and means of sensor 100 can be applied in numerous ways, either to modify the sensor response characteristics, or to achieve other objectives such as manufacturing cost reduction. The sensor can be provided with an adhesive backing, or it can be otherwise affixed in the diaper. As with any high volume disposable product, it is advantageous to employ biodegradable materials wherever practical. A releasable electronic coupling and monitor-retention portion 450 of the sensor can protrude from the diaper and be disposed on a top front diaper surface 474, either as in the add-on unit as shown in Fig. 2A and Fig. 2B, or by utilizing various additions or modifications to a diaper such as are shown in Fig. 22A, Fig. 22B, Fig. 22C, Fig. 22D and Fig. 22E.

The Sensor

Sensor 100 is typically a multi-layer assembly, resembling a pad or strip, that is applied directly to, or incorporated within a diaper or other article with which it is to be used. A preferred add-on embodiment of the sensor, shown in Fig. 1, has a top 102, a bottom 104, two side edges 105, a distal end 106 and a proximal end 108. Shown to the right of a dashed fold line 342 (indicating the line at which the sensor is designed to fold over the top front edge of a diaper as shown in Fig. 2A), is releasable electronic coupling and monitor-retention portion 450. Portion 450 of the sensor includes means for the attachment and

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retention of monitor/alarm 500, and is shown in the close-up perspective view of **Fig. 5A**. The preferred disposable add-on embodiment, as introduced above, is further illustrated in **Fig. 3**, showing the various superposed layers. For clarity, removable bottom protective layer 110 and a similarly strippable top protective cover 455 (shown in **Fig. 5A**), are omitted.

5 The layers of the embodiment of **Fig. 3** are presented in the magnified cross-section views of **Fig. 3A**, **Fig. 3B** and **Fig. 3C**. The relevant locations and orientations of these cross sections are indicated in **Fig. 3**. This embodiment of sensor 100 is also shown (including all layers) in the vertically-exaggerated side elevation view of **Fig. 4**. In **Fig. 4**, the layers include, from bottom to top: removable protective layer 110 (comprised of a releasable

10 adhesive fastening tape 116, a wrapping portion 114, and a strippable portion 112), a lower connecting/attaching layer 452, a monitor/alarm retaining flap layer 460, an optional monitor/alarm locating block 470, a tab stiffener 166, a lower relatively impermeable layer 150, an electrically conductive elements layer 200, a lower porous/absorbent layer 250, an upper relatively impermeable layer 300, second porous/absorbent layer 350, cover layer

15 400, and strippable top protective layer 455. These layers, including the dimensions thereof, will be described in greater detail below, particularly so with regard to the same preferred embodiment. The layers are shown separately in **Fig. 6**, **Fig. 7**, **Fig. 8**, **Fig. 9**, **Fig. 10**, **Fig. 11**, **Fig. 12**, **Fig. 13**, **Fig. 14**, **Fig. 15**, **Fig. 16** and **Fig. 17**, respectively. Just as certain sensor modifications may be required to adjust for different embodiments and use

20 environments, differing size diapers will require that at least some of the dimensions vary (preferably, only the lengths of certain layers), but not necessarily in direct proportion to the differences in diaper size. The detailed description of layers 452, 166, 150, 200, 300, 460, 470 and 455, comprising releasable electronic coupling and retention portion 450 of the sensor, will be addressed later in the specification. This is so that the layers comprising the

25 "inside-the-diaper" portion of the sensor (as shown to the left of fold line 342 in **Fig. 1**, **Fig. 3** and **Fig. 4**), can be first addressed as a key functional structure.

"Bounding" and the Effects of Adhesives, Coatings and Inter-Layer Attachments

In describing the various layers of sensor 100, the preferred disposition of adhesive means may optionally be indicated in the layer names, e.g., by calling layers 150 and 300

30 "double-sided adhesive layers." As will be apparent to those skilled in the art, adhesives can be disposed on appropriate portions and surfaces of various layers including others such as 200, 250, 350 and 400, in order to achieve the proper assembly of the sensor, or alternatively, processes such as heat bonding or ultrasonic or laser welding can be

35 employed to eliminate the use of adhesives. The physical surface-to-surface attachment vs. simple juxtaposition of layers can be significant to the proper functioning of the sensor due to "bounding" effects on the liquid absorbency and flow properties of the porous/absorbent layers. Establishing a boundary, or "bounding" a surface of a thin absorbent layer, by sealing it with an adhesive or other impermeable coating, blocks off air contact across the

40 surface that would otherwise break (reduce) the average magnitude of cross-sectional pore capillary tension that pulls a liquid transversely through the layer. Such bounding causes a liquid to spread more rapidly in the layer — while decreasing or eliminating the layer's

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surface absorption ability -- in other words, its ability to "collect" through the surface that is bounded. For example, completely bounding both the top and bottom of a thin absorbent layer would tend to maximize the transverse or lateral spreading rate of a liquid, but would also eliminate its surface absorbent ability. (Note that the terms, "transverse" and "lateral" will be used interchangeably in this discussion to denote spreading flow in a layer of material, as opposed to "normal" or "through" which interchangeably denote flow "into" or "out of" a layer or layers relatively perpendicular to the approximate plane of the layer(s).) Surface absorbency and lateral spreading rate may be tailored by adjusting the "open area" or percentage of surface that is not bounded (e.g., by providing "pin-holes" or other interruptions in the bounding adhesive or coating, or by use of a dissolvable coating). Lateral spreading can also be accomplished by virtue of the relative permeability or absorbency of adjacent layers, such that the choice of materials employed can determine the primary direction of flow through and around the sensor. Thus, the term "relatively impermeable" is employed to describe layer 300 in order to stress its function of providing a baffle between the sensing means 200 and the origin of liquid to be sensed.

In some cases, as explained above, physical attachment via adhesive is preferable and can contribute to calibration of the sensor for desired alarm response. It also helps maximize through-flow into the diaper. For example, as shown in **Figs. 3B** and **3D**, lower absorbent layer 250, upper impermeable layer 300, and upper absorbent layer 350 are preferably adhesively joined by double-sided adhesive on layer 300, such that adjacent portions 258/358 of the two absorbent layers 250 and 350 are maintained in constant, direct contact. In the embodiment of **Fig. 3B**, this contact is through the openings indicated by reference number 320. This constant and predictable contact is important to the "flow-splitting" characteristics of the sensor, whereby the urine that is initially absorbed through cover layer 400 into absorbent layer 350 wicks laterally across the central portion of impermeable barrier layer 300 and through contacting portions 258/358 and portion 356, preferentially flowing "downward" into the diaper. This preferential through-flow continues until the diaper's rate of surface absorption diminishes (with increasing saturation of its absorbent bulk and/or rapid flow into the surface) below that of absorbent layer 250, at which point at least a portion (or an increased portion) of the total flow does not go into the diaper, but instead laterally splits off from the main flow and goes through absorbent layer 250 and therethrough to the conductive layer 200. Another example of advantageous adhesion of absorbent layers is that the transfer efficiency of relatively high-volume flow through the sensor into the diaper via contact portion 356 (or via a series of "spillway" openings 310 shown in **Fig. 3B**). This is substantially increased by securely disposing contact portion 356 adjacent and in fluid communication with the diaper (or adhering the area surrounding the openings 310 to the diaper surface). This ensures that the upper absorbent layer 350 remains in constant direct contact with the diaper to provide capillary continuity through or around the otherwise impermeable layer 300.

In other portions of the sensor, however, physical attachment is not preferable. For example, as can be seen in **Fig. 3B**, cover layer 400 can be "free floating" or affixed with respect to the top surface of upper absorbent layer 350. By leaving layers 350 and 400

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juxtaposed but not adhered, they remain unbounded, thus enhancing the ability of layer 350 to quickly absorb an initial flow of urine, and preventing "splash-back" in the region of the diaper covered by the sensor. A lack of adhesion here also contributes to skin-contact comfort and the pliability of the sensor, and thus its conformance to the ever-changing shape of a diaper. This is because cover 400 can readily slide over layer 350, thereby increasing the flexibility of the entire sensor.

The Bottom Removable Protective Layer of Sensor 100

Removable protective layer 110 in a preferred add-on embodiment is typically employed as packaging to preserve the cleanliness of the sensor, while permitting it to be folded or rolled. Layer 110 also facilitates application and assembly of the system by providing strippable protection of certain preferably adhesive surfaces of the sensor. As illustrated in Fig. 4 and Fig. 6, layer 110 has strippable portion 112 that releaseably adheres to, and has approximately the same width as (or preferably slightly greater width than), double-sided adhesive layers 300 and 452. The material used for strippable portion 112 must be consistent with the characteristics of the adhesive to which it must releaseably adhere, such as a thin paper with a nonporous plastic or waxy coating having characteristically low bond strength with the adhesive to be covered. (Such covering material is typically specified for best compatibility with specific adhesive tapes from manufacturers such as 3-M.) Extending on either side of strippable portion 112 is an optional wrapping portion 114, which extends sufficiently to fold around the entire sensor means 100. The material used for wrapping portion 114 must be thin, light, foldable, and disposable; such as polyethylene or vinyl sheet, preferably about 0.001-inch in thickness or less. It can optionally be fabricated of the same material as strippable portion 112, with the attendant advantage of reducing the number of materials required and eliminating a lamination step in the manufacturing process. At one end of wrapping portion 114 is adhesive tape piece 116 for retaining the assembly in a clean folded or rolled condition prior to use. Wrapping portion 114/116 may not be needed if sensors are bulk-packaged (e.g., in a plastic bag of sensors stacked flat) and, as mentioned, entire protective layer 110 is not required in a pre-incorporated disposable diaper embodiment of the sensor.

The "Inside-the-Diaper" Portion of Sensor 100

Lower relatively impermeable layer 150 shown in Fig. 3 and Fig. 11, can serve as means for affixing sensor 100 to the diaper or other environment of use. As illustrated in Fig. 3B, layer 150 has a center core 152, optionally but preferably provided with upper 154 and lower 156 adhesives. Layer 150 also provides structural support, holding electrically conductive layer 200 in place, maintaining elements 202 and 204 nominally parallel and a pre-determined distance apart and also defining a channel 160 therebetween. By being fabricated of liquid resistant or impermeable material(s), layer 150 also serves to trap moisture in channel 160. Layer 150 also adheres to portions of absorbent layer 250 and therethrough to the remainder of sensor means 100, which is thereby also affixed to the diaper. The material for impermeable layer 150 is typically a thin (approximately 0.001 inch thick), flexible but

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dimensionally stable tape of liquid impermeable paper or preferably plastic such as acetate, vinyl, polyethylene, polypropylene, polyester, or the like. Layer 150, and therefore core 152 is, with the exception of conductive layer 200, the narrowest layer of sensor means 100. In a preferred embodiment, as shown in Fig. 3 and Fig. 11, layer 150 is approximately 0.75 inches wide and 0.003 inch thick, with an optionally narrower portion 162 in the front (near end 164). This narrower portion approximately matches the overall width of electrically conductive elements 202 and 204 of layer 200 so that upper adhesive 154 of layer 150 is not exposed at the front connective end 162 of layer 150 above tab stiffener 166 as shown in Fig. 5A. Tab stiffener 166, shown in Fig. 3C and Fig. 10, is fabricated from a preferably thicker, stiffer material than core 152 (such as 0.010 inch thick polyester sheet) and is adhered to the lower adhesive 156 of layer 150. Tab stiffener 166 serves as structural support for layers 150 and 200 and preferably also as an active spring element for the releasable connection between sensor 100 and monitor 500 as shown in Fig. 5A and Fig. 5B. The combination of tab stiffener 166 with the front portions of layers 150 and 200 comprises male connector tab assembly 170 of sensor 100, as shown in Fig. 4 and Fig. 5A. As will be further described with respect to the releasable electronic coupling and retention portion 450 of the sensor, this tab assembly also helps locate and retain monitor unit 500 when it is connected to sensor 100 and installed on a diaper for use, as shown in the close-up side view of Fig. 5B. As shown in Fig. 11, portion 162 of impermeable layer 150 is, in a preferred embodiment, 0.5 inches in width and tab stiffener 166 is preferably 0.75 inches in width which is slightly less than the width of a recessed connector-receiving portion 600 of monitor/alarm unit 500 which receives tab portion 170 of the sensor for electrical and mechanical connection purposes as shown in Fig. 20. The material used for upper adhesive 154, as shown in Fig. 3A, Fig. 3B and Fig. 3C, is selected to form a strong, preferably permanent attachment to conductive layer 200 and absorbent layer 250. Adhesive 154 should be a non-absorbent, non-transmissive adhesive, like the pressure-sensitive adhesive on typical 3-M "Scotch" brand tapes. Alternatively, it can be a layer of heat melting adhesive, or one or more of the material surfaces themselves can be melted together for attachment. The material used for lower adhesive 156 is selected to releaseably adhere to protective layer 110; it can be the same as upper adhesive 154, depending on the nature of strippable portion 112 of protective layer 110. Layer 150 can be obtained with the adhesives 154 and 156 already applied or alternatively, the adhesives can be applied as part of the assembly process. Layer 150 may preferably be cut from 0.75-inch wide, double-sticky tape (such as 3-M type 665), which is readily available pre-spooled in the desired width.

In a pre-incorporated disposable diaper embodiment of the invention, lower adhesive 156 can optionally be replaced by alternative means (such as heat bonding or use of a sewn portion or a recessed channel or folds in the diaper's absorbent core material) for receiving/affixing the sensor means in place within the diaper, or the sensor can be instead attached to an inner cover layer or other part of the diaper, as proves most economical for manufacturing.

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As illustrated in Fig. 12, conductive strips layer 200 has first 202 and second 204 conductive members. Members 202 and 204 each have an outer edge 206 and an inner edge 208. They are maintained substantially parallel to each other by top adhesive 154 of layer 150, and (most simply) a fixed distance apart (preferably about 0.010 to 0.125 inch and most preferably 0.045 inch). The materials used for conductive members 202 and 204, and their dimensions, taken together with those of channel 160 and the material of which they are made, in part determine the sensitivity of sensor 100 and the entire system. Conductive members 202 and 204 can be made of different materials, or preferably the same material, such as laminated thin metallic foil (e.g., 0.001 inch thick aluminum), or vacuum-deposited metal or semiconductor, or printed conductive ink, paint, ionic jell, dissolvable salt or other liquid-enabled conductor, or doped polymer material.

The spacing of conductive members 202 and 204 which defines the width of channel 160 may be set (or even vary) over a considerable range (e.g., about 0.01-0.5 inch), but with suitable compensation in the choice of certain electronic component values in monitor unit 500 to achieve the desired threshold of sensitivity. The conductivity of urine and feces varies over a wide range and careful compromise in the setting of design parameters is required to reliably detect both urine and feces. Even with appropriate component value selection, however, other factors tend to make the preferred range of spacing (as well as conductor width) more limited in practice. In general, too small spacing of channel 160 could cause production difficulty to ensure that the two conductive strips never touch or short (including at end 164 where the sensor attaches to a set of monitor unit connecting contacts 620, 622 and 624 as shown in Fig. 5B and Fig. 20). Also, too small spacing increases the susceptibility of the sensor to damage or to irrelevant contaminating particles which might accidentally bridge the conductors. Similarly, condensation from nearby perspiring skin or even high ambient humidity could be troublesome if the spacing is too small. Up to a point, the smaller the spacing, the more electronically noise-resistant the system can theoretically be made, but at the expense of more power consumption because the current flow between the conductors is greater in magnitude during sensing, especially when elimination material is bridging the conductors. On the other hand, too large a spacing necessitates unrealistically high reference impedance to detect the presence of relatively low-conductivity feces, particularly of the drier variety. Larger spacing also means that a series of feces-intrusion openings 252, 330, 352 and 410 (as shown in Fig. 13, Fig. 14, Fig. 15 and Fig. 16, respectively), need to be wider to span both conductors and relatively more feces would need to be present for reliable detection. Too large openings could also undesirably allow the diaper wearer's skin to press into the openings and possibly to touch or even bridge the conductive strips.

Members 202 and 204 can have different widths (about 0.305 and 0.130 inch, respectively, in a preferred embodiment) but preferably the same thickness (typically 0.001-inch or less), to minimize perceivable stiffness and destructive stress in repeated flexure of the sensor. In practicality, both the width and the spacing of the conductive strips may be chosen to coincide with the minimum practical connector spacing and contact overlap at the connector tab portion 170 (as shown in Fig. 20). Minimizing the total area of layer 200 is

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desirable, because the total exposed conductor area, divided by the average conductor gap, is proportional to the total electrical capacitance of the sensor. The higher the sensor capacitance, the greater the electronic and electrical noise susceptibility of the system, and also the greater the required power to operate the sensor. Finally, relatively larger active sensor area (defined by the outer "footprint" of conductive elements 200) would undesirably result in greater obstruction of flow from source (the diaper wearer) to bulk absorber (the diaper), because lower impermeable layer 150 (which separates conductive strips 202 and 204 from the diaper layers below) allows no direct downward (through) flow anywhere in this lengthwise central area of the sensor.

As previously described, either member 202 or 204 can be the larger or smaller without affecting the function of the sensor means. In a preferred embodiment, the wider conductive strip 202 is preferably used to bridge the pair of contacts 620 and 622 in monitor unit 500 where the ends of the strips are brought out into either a flexible or rigid connector tab configuration (as shown in Fig. 20.). This allows the simple insertion of the connector tab portion of the sensor into the monitor unit (as also shown in Fig. 5B) to conveniently serve as the only power-on/off control needed in the system. Constant-width over the entire length of the strips is desirable for manufacturing with roll-fed metal foil conductive materials, but is obviously not necessary for either deposited or printed-on conductive strips, in which case the width of one strip could easily be made larger than the other only at the connector end, or the elements of layer 200 could take various other shapes; for example, they could be disposed in lattice or net-like form rather than solid strips, to reduce electrical capacitance and material costs while still covering the necessary areas and providing the desired functions.

As will be further discussed with respect to monitor/alarm unit 500, the conductive strips are subjected, via releasable connection to the monitor unit circuit, to time-spaced (approximately every 3-seconds) brief (approximately 0.1-sec duration) low-voltage (under 3v) fast rise-time (preferably less than 1 u-sec) square-wave pulses which are variably conducted by any material in "trap" channel 160 between the conductor strips, to allow a proportional average electrical current (ranging from zero to approximately 1 micro-ampere) to flow between the strips during the duration of each pulse. The magnitude of current depends on the "bulk ionic" and "skin" conductivity of the material bridging the conductor strips as well as the geometry and spacing of the effective current path. A level of resulting current flow during any of these pulses that exceed a preset threshold level preferably causes the monitor unit to either "beep" audibly or flash a visible alarm to signal the caregiver that the diaper or other absorber needs changing. As previously mentioned, double or multiple pulses are preferred over single ones – for more effective alarm communication to the caregiver.

As illustrated in Fig. 3, and Fig. 13, porous, absorbent layer 250 is generally rectangular in shape, somewhat wider than double-sided adhesive layer 150, and has a series of elongated openings 252 disposed toward its distal end 254. (These openings can alternatively be described as conduits, channels, passageways, perforations, holes or the like, and are provided for feces-specific detection purposes – as shall be fully explained as

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the other layers of sensor 100 are described.) The length of layer 250 nominally extends from just over fold line 342, when installed at the front rim of a diaper, down and throughout the full length of the portion of the sensor that goes inside a diaper. Layer 250 is made of a typically cellulose-based, highly absorbent paper or cloth, or similar natural or synthetic, hydrophilic material of either woven or non-woven composition, the choice of which will depend on manufacturing economics and the purposes to be accomplished by the layer. Its thickness, in a preferred embodiment, is about 0.01-0.06 inch (uncompressed) but may be selected from a considerable range, the choice of which primarily affects the response delay time of the sensor to urination events. Greater thickness increases the relative liquid buffering and volume carrying abilities of the layer, as opposed to the transverse spreading rate of liquid through the layer. The relative width, and particularly the material and composition of absorbent layer 250 also contributes to determine its characteristics, as described below.

A significant characteristic of liquid-porous (absorbent) media in general, is the average pore size or channel dimension of the material, which, along with the surface tension between the material and a given liquid, determines its average "capillary tension" or relative ability to draw liquid from an adjacent absorbent porous material. A material with relatively smaller average pore or channel size is able to draw liquid from an adjoining volume of similar material having relatively larger average pore or channel size. Moreover, for low viscosity liquids, the smaller the average pore size, the faster a material will absorb liquid because absorption rate is proportional to average capillary tension (measured in units of vacuum), which in turn depends on the average empty-pore surface-to-volume ratio as well as the % of empty pore capacity currently available to hold more liquid (i.e., the available "absorbent capacity", usually expressed as a % by either volume or weight).

The instantaneous absorption rate across a surface (such as the inside of a diaper) changes, depending on the balance between how rapidly liquid is arriving at the exposed surface (to be absorbed) and how fast it can be wicked away into the bulk of the material's volume. As available absorbent capacity diminishes over time, due to accumulation of liquid throughout its bulk, the maximum (usually initial) absorption rate into the surface is reduced because the average capillary tension is reduced. If liquid arrives at the junction of two materials having substantially different capillary tension, such as the interfaces 259 and 356 (and to a lesser extent 260, due to being shielded by 300 from direct contact with 350) between a diaper surface (such as 400-B) and porous layers 250 and 350 of sensor 100, relatively more (or even virtually all) of the flow will go into the material with the higher tension (initially the diaper), until the tension of the diaper material eventually drops (due to liquid urine accumulation) to a lower value than that of layer 250. This "splitting" of the flow may also happen at any time, if the incoming flow is so fast as to "overwhelm" the maximum absorbent rate capacity of the diaper surface, regardless of whether the diaper's total absorbent capacity has become reduced.

As illustrated, e.g., in Fig. 3, Fig. 3A, Fig. 3B and Fig. 14, second relatively impermeable layer 300 is the backbone (and for certain processes the manufacturing substrate) of sensor 100. As with layer 150, layer 300 has a center core 302, optionally but

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preferably provided with an upper 304 and a lower 306 adhesive, each made of materials similar to, or as described with reference to layer 150, except that in a preferred embodiment as illustrated, layer 300 is approximately 1.5 inches in width. Also in this embodiment, layer 300 is preferably approximately 0.001-0.003 inch thick, and can be punched from 1.50-inch

5 wide, pre-spooled, double-sticky paper or plastic tape, preferably being relatively liquid impermeable and hydrophobic (i.e., tending to not be "wetable" by aqueous solutions such as urine), and having good dimensional stability, high torsional flexibility and suitably aggressive adhesive (such as type DT-42, manufactured by Manco, Inc. of Westlake, Ohio).

In the embodiment of Figs. 3B, layer 300 is provided with a plurality of openings 310 and 320, each preferably extending through core 302 and both adhesives 304 and 306, primarily disposed toward the outer edges 308. In addition to flow-related functions, this plurality of openings contributes to the mechanical flexibility and compliance of sensor 100, by reducing the overall stiffness of its combined layers. The first series of openings 310 is preferably symmetrically disposed towards outer edges 308 of layer 300. While most

10 shapes will serve the function, rectangular or elongated outer openings are preferred. This provides the best balance in the use of available surface area for the impermeable adhesion of layer 400 to layer 300 (along edges 308 as shown in Fig. 3B), without compromising either the structural integrity of layer 300 or the sensor's capability to permit rapid liquid flow into a diaper. As shown in Fig. 14, each of openings 310 have a front-most edge 312, rear-most edge 314, outermost edge 316 and innermost edge 318. The second series of

15 openings 320 (also shown as being preferably rectangular for similar reasons, although most other shapes could be employed) is preferably symmetrically disposed inward of openings 310 (towards the center of layer 300), with the centers of the openings approximately co-linear with the midpoints between each front-most 312 and rear-most 314 edge of openings 310. This relatively staggered disposition of openings 310 and 320 serves to maximize the structural integrity of layer 300 without impeding through-flow. It also helps ensure that, regardless of the path taken by any outward flow across the top of impermeable layer 300, the flow distance to reach the diaper through openings 310 and over edges 308 will be minimized, while at least some of the flow will be practically certain to enter openings

20 320 and thereby be conducted into absorbent layer 250. The outermost edges 322 of second series 320 is positioned closely adjacent the outer edge 256 of absorbent layer 250 and the innermost edge 318 of openings 310, most preferably with outermost edge 256 directly aligned midway between edges 318 and 322.

Through this arrangement, outermost direct contact portion 356 (whether through the first series 310 or not) acts as a "spillway" to conduct liquid rapidly and directly to the diaper, while the innermost direct contact portion 258/358 (whether through the second series of "flow-splitting" openings 320 or not) conducts liquid into the absorbent layer 250 and to some extent therethrough to the diaper. The capillary absorbent characteristics of the material employed for layer 250, relative to the material of the diaper surface, will determine

35 if, and at what rate, such liquid is wicked transversely inward through layer 250 towards channel 160 -- as opposed to such liquid being absorbed either completely or partially downward into the diaper through the bottom surface portion of layer 250 (outward of the

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side edges of shielding/trapping impermeable layer 150). The arrival of such liquid, wicking laterally inward through layer 250 and thus to channel 160, will increase the measurable conductivity between members 202 and 204. Upon reaching an appropriately pre-determined threshold level of conductivity (or change, or rate-of-change of conductivity, or similar change in any other suitable property resulting from the arrival of such liquid), the circuit of monitor/alarm unit 500, releaseably connected to conductive members 202 and 204, is effectively triggered. This condition then initiates an alarm indication by the monitor unit that the diaper needs changing.

A third series of openings 330 in layer 300 is preferably shaped like and disposed directly above and in communication with elongated openings 252, and therethrough to conductive members 202 and 204. As shown in **Fig. 3**, **Fig. 13** and **Fig. 14**, openings 330 and 252 are preferably disposed along the central portion of sensor 100, towards the distal end, approximately midway between some of openings 320 and extend laterally outward approximately to a line connecting the innermost portions 324 of openings 320. It is further preferred to have a matching number of elongated openings 330 and 252. In **Fig. 3A** it can be seen that, while other shapes will serve the function, the laterally elongated shapes are particularly suited to efficiently conducting semi-solid and liquid fecal matter to channel 160, thereby directly contacting conductive members 202 and 204 to facilitate the detection of feces, which had heretofore presented considerable difficulties. The location and concentration of openings 330 and 252 only towards the rear, or distal end, of sensor 100 disposes these conduits towards the most likely concentration of feces, and posterior to the most likely origin of urine, and particularly away from directly-impinging streams of urine. This arrangement prevents erroneous pre-triggering of the system, by eliminating the likelihood that directly-impinging urine streams will enter through the feces-selective detection openings to contact conductive layer 200.

Absorbent layer 250 is bounded by means of adhesive contact on the bottom side with layer 150 (except those portions in direct contact with conductive elements 202 and 204), and also by adhesive contact on the top side with layer 300. This bounding causes the lateral spreading rate within layer 250 to be increased and the "capillary trap" nature of channel 160 (defined by the inner edges 208 of members 202 and 204, the upper adhesive surface of layer 150, and the lower surface of layer 250) to be enhanced. Also, because channel 160 is filled with the somewhat resilient porous media 250 (except in the locations of feces-selective detection openings 330 and 252), a sufficiently strong capillary nature is imparted to channel 160 for retaining the liquid material to be sensed. This "capillary trap" is capable of retaining enough relatively conductive elimination material, long after it initially arrives into the trap, to eliminate the need for any functional "latching" of an over-threshold level of conductivity condition (as measured across conductive elements 202 and 204) on the part of monitor unit 500. This feature of the sensor is important because it enables the monitor to have very high electronic sensitivity to the very low typical conductivity produced by bridging the conductive strips 202 and 204 with fecal matter – and yet to operate in a repetitively self-correcting (i.e., "self-resetting" as opposed to "latching") mode in the presence of electrical noise or interference, or any momentary bridging (relative shorting) of

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the conductor strips for any reason. As mentioned previously, a common problem with electronic sensing devices that "latch" on the momentary attainment of a preset threshold level of any measurable quantity is that they can, particularly if operating at high sensitivity, be inappropriately and permanently triggered by insignificant conditions.

5 Considering other design aspects involving the interrelationships of layers, layer 150 has to be wider than the overall "footprint" of conductive strips 202 and 204 because otherwise, unless the strips were made of conductive adhesive, there would be no exposed adhesive area to stick to absorbent layer 250 other than in the narrow gap between the strips. If conductive adhesive is used, a non-adhesive portion should be provided at the
10 connector end of strips 202 and 204 (where the strips themselves also function as the sliding connective elements for releasable communication with electronic monitor unit 500 as shown in Fig. 5A and Fig. 5B). Layer 150 is also preferably sticky on its bottom to adhere the whole sensor to the diaper along the lengthwise centerline. As previously mentioned, this is desirable for secure attachment – and also for adequate conformance by the sensor
15 to the diaper's varying shape. This also helps maintain good capillary contact of the exposed areas of the bottom of absorbent layer 250 (at edges 256 outboard of layer 150) with the diaper surface -- thereby facilitating both maximum urine through-flow and appropriate monitor system response.

 In still other interrelating aspects, impermeable layer 150 "protects" the capillary well or trap of channel 160 and also the lateral flow (coming from around impermeable layer 300 and through contact portions 258/358 and continuing inward through absorbent layer 250) from being uncontrollably "robbed", or depleted of urine, by the diaper surface from below. The more exposed surface area 259 of absorbent layer 250 that is in contact with the diaper
20 between layer 300 or flow splitting holes 320 and the outer edges of impermeable layer 150, the less sensitive the response of the sensor becomes (relative to the diaper surface absorbency), because the lateral flow that would otherwise cause triggering of the monitor unit is relatively more likely to be absorbed into the diaper before it can get to capillary trap 160 between conductive elements 202 and 204. Conversely, if direct contact portions 258/358 or the flow-splitting holes 320 are laterally repositioned relatively inward, to be
25 partially or even completely above impermeable layer 150, or if layer 150 is made wider, the sensor response can thereby be changed, if desired, to allow triggering of an alarm after a certain minimum volume of urine has been discharged, with less or even practically no dependence on the remaining absorbent capability of the diaper below. Thus, the sensor can be designed to split flow between itself and a diaper, transferring a proportion of the flow
30 to layer 250 in order to model (as opposed to measure) the effective absorbent capacity of the diaper vis-a-vis the volume of urine discharged; this is particularly advantageous in the add-on (as opposed to the incorporated) embodiments of the invention.

 Again referring to Figs. 3B and 3D, the relative width of layer 150 vis-à-vis the lateral positioning of direct contact portions 258/358, 259 and 260 (or flow-splitting holes 320) is
35 thus one means usable to easily "fine-tune" the urination-response of sensor 100 to reflect the desired traditional criteria (and to adjust for diaper material properties). "Coarse tuning" can be done by selecting, relative to the diaper materials, the average pore size or other
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appropriate properties of absorbent layers 250 and 350. (These layers are made of materials normally available "off-the-shelf" with only stepwise-varying and limited range of absorbency properties.) A preferred combination of parameters must produce the desired response sensitivity and also have sufficient areas for adhesion (or other means of attachment) on layer 150, with the narrowest possible core 152. This narrowness is important because the smaller the overall "footprint" of impermeable layer 150, the more "transparent" the whole sensor can be made to the rapid flow of urine into a diaper -- and also, the more flexible and compliant the sensor can be made.

As previously explained, the difference in respective capillary or absorbent tension at the junction of layer 250 and the diaper surface is a key means of "flow-splitting" for the purpose of monitoring diaper condition during and after urination events. However, triggering of the sensor does not necessarily depend on what the overall "degree of saturation" or "filled percentage" of layer 250 itself is at any given time -- either as compared to the diaper surface, or absolutely. This is true, because only part of layer 250 needs to reach saturation in a cross-sectional "conduit", of even very small dimensions. This conduit can become gradually filled with sufficient liquid volume, in response to urination events, to reach and trigger the detector means (by bridging members 202 and 204 in channel 160). Therefore, in an alternate sensor embodiment, even a non-absorbent capillary layer or other liquid transport device could serve the function of layer 250 in conducting liquid to a sensing means, leaving the surface-condition discrimination function to a separate element, or even eliminating it entirely. Because "flow-splitting" in conjunction with liquid transit delay can be employed to somewhat proportionally track the total volume of flow into a diaper (as opposed to, or in addition to, monitoring the diaper's remaining surface absorbent properties), this mechanism can also be exploited to modify the sensor response. For example, if lower absorbent layer 250 is made thicker, relative to its area, it will tend to act more like a "time delay" or "proportional splitting" element, and less like a "tension discrimination" element, because at greater distance away from the diaper surface (vertically), the lateral flow is less affected by the diaper. This is particularly true at the top surface of layer 250 that is bounded by upper impermeable layer 300. Alternate embodiments of sensor 100 could be configured with materials and dimensions chosen such that the delay in triggering of the sensor after one or more elimination event(s) depends primarily or even completely on the time-delay of lateral propagation as described above (instead of primarily on relative capillary tension of the contacting surfaces). Such arrangement would achieve substantially the same purpose of allowing the diaper to function effectively (i.e., by allowing it to absorb some quantity and/or relatively low flow rate of elimination material during a delay period) before causing monitor/alarm unit 500 to produce an on-going "ready-for-diaper-change" indication. For example, larger portions or even the entire lower surface of absorbent layer 250 can be bounded by an impermeable layer, such that elimination material can enter layer 250 from either above (such as through holes in baffle layer 300) or alternatively from around a baffle layer. Such material would then travel laterally, over a period of time, to the sensing point, triggering a detector. Holes through the impermeable baffle can also extend through layer 250 and/or the lower bounding layer to

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allow more of the elimination material to flow through the sensor into the absorber.

In a variation of the preferred embodiment, as suggested above, it is also possible for an upper layer or layers of the diaper itself to serve the purpose of absorbent layer 250, relative to the rest of the diaper beneath it. In this case, the detector means, such as the
 5 conductive strips 202 and 204 in the preferred embodiment, could be disposed on the bottom of impermeable layer 300. A portion of the same layer 300 could also be adapted to form a relatively narrower tab-like connector structure at its proximal end (either with or without additional laminated layers) to connect with a monitor unit. Such configuration could thereby also eliminate the need for layer 150. This approach is shown with reference to
 10 connector tab assembly portion 170 of the pre-incorporated sensor embodiment in **Fig. 22C**. Such arrangement would not, of course, benefit from the liquid-trapping and shielding effects provided by layer 150 in the preferred embodiment, but it could offer even lower sensor cost. It would also be possible to dispose a material having absorbent properties that are different from the rest of a diaper, under an impermeable layer and in contact with
 15 the sensing means (such as conductive elements 202 and 204), to effectively trap moisture or liquid, thereby serving the function of capillary trap portion 160 and facilitating an appropriate sensor response.

In still other alternate embodiments, any appropriate detector means could be located under (or shielded by) the effective baffle of a relatively impermeable element (such
 20 as layer 300) to receive elimination flow presented through openings in (or around the edges of) such a baffle. This flow would appropriately affect the detector means by causing a change in a suitable measured quantity due to the combination of sufficient liquid accumulation and/or flow. The detector means would then cause an alarm signal or indication to be produced, reflecting a desired set of criteria for appropriately determining the
 25 need for elimination-absorber changing (or at least, inspection).

As illustrated in **Fig. 3, Fig. 3A, Fig. 3B, Fig. 4 and Fig. 15**, porous, absorbent, collecting/spreading layer 350 is generally rectangular in shape, at least the same width as layer 300, but preferably at least slightly wider to provide direct contact portions 258/358 and 356, also forming a floating soft edge. Absorbent layer 350 also has a series of elongated
 30 openings 352, preferably shaped like and disposed directly above and in communication with an equal number of elongated openings 252 and openings 330 for feces-specific detection purposes, as will be further explained below. The materials for absorbent layer 350 may be approximately the same thickness and selected from the same types as used for layer 250. In a preferred embodiment, however, layer 250 may be designed to have
 35 somewhat lower initial absorbency relative to the contacting diaper layers for the purpose of directing urine flow preferentially into the diaper until the diaper's absorbency is significantly reduced. On the other hand, the absorbency of layer 350 is chosen to be as high as is practical, to prevent urine "splash-back" and to readily collect urine flow impinging anywhere on its upper surface. Layer 350 also assists in preventing premature triggering of the sensor
 40 by absorbing and buffering a significant volume of urine, and having the capillary or wicking characteristics to rapidly conduct fluid towards the outer edges 354. Preferably, by bounding absorbent layer 350 by directly adhering it to impermeable layer 300, or by

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otherwise coating it with impermeable material, the lateral liquid capturing and/or spreading characteristic of layer 350 is enhanced. Such direct adherence of both absorbent layers 250 and 350 to the bottom and top surfaces, respectively, of impermeable layer 300 also facilitates rapid and predictable flow of liquid through direct contact portions 258/358 or "flow-splitting" holes 320 in layer 300, by maintaining the mutual capillary contact of absorbent layers 250 and 350 through these holes, as can be seen in **Fig. 3B** and **3D**.

As shown in **Fig. 3A**, urine is prevented from flowing indirectly to the conductive elements 202 and 204 via seepage (i.e., capillary flow) from porous layer 350 through the feces-specific detection openings 352, 330 and 252, because these openings in both absorbent layers 350 and 250 are aligned with, (and in some embodiments slightly larger than) openings 330 in layer 300 such that the two absorbent layers do not touch each other through impermeable (and preferably hydrophobic) layer 300. This capillary gap, as indicated by reference number 332, eliminates any seepage path for urine through the effectively selective feces-specific detection openings. As will be apparent to those skilled in the art, the manufacturing method used to punch or otherwise create feces detection openings 352, 330 and 252, must cut cleanly -- so as to not allow capillary fragments of layers 350 and 250 to remain in the area of openings 330 in layer 300.

It is possible, in an alternate embodiment, for layer 350 to have suitable openings in its surface and to be made wide enough to wrap completely around impermeable layer 300, and thus also function as absorbent layer 250. In this case, adhesive could be applied to the bottom outer edges of combined layer 250/350, or some other means could be used to hold sensor 100 to the diaper.

Impermeable layer 300 can be made similar to or the same width as impermeable layer 150, so that there is no need for punching either "spillway holes" 310 or "flow-splitting holes" 320 through layer 300. In this case, suitable adhesive or other means (such as heat-bonding) could be employed to keep the absorbent layers together (at least in places) and also optionally to hold the sensor in good contact with the diaper surface. In an embodiment wherein the sensor is incorporated into a diaper, the surrounding layers of the diaper could serve this purpose. If layer 300 is made narrower to eliminate holes 310 and 320, layer 300 can still be wider at the proximal end of the sensor forward of some point near fold-line 342, or it can be affixed to or used with a separate wider assembly for the various purposes of attachment to, location of, and retention of monitor unit 500 at the top front of a diaper. As previously stated, various aspects of the proximal ("outside the diaper") portion of the sensor structure shall be further described later in the specification, with respect to the releasable electronic coupling and retention portion 450.

As illustrated in **Fig. 1**, **Fig. 2A**, **Fig. 2B**, **Fig. 3**, **Fig. 3A**, **Fig. 3B**, **Fig. 4** and **Fig. 16**, cover layer 400 is the top most layer (when the sensor is installed on a diaper for use). It contacts the wearer's skin and is designed to provide comfort and protection from contact with the other layers. It has a top surface 402, a bottom surface 404 and outer side edges 406. Layer 400 must be soft, non-absorbent, and preferably highly porous or liquid transmissive, so as to be minimally obstructive to urine flow, while maintaining a relatively dry surface in contact with the skin. In a preferred embodiment, layer 400 can be made from

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a hydrophobic material, so that although urine can still be rapidly absorbed through its mesh of openings by layer 350, the top surface otherwise remains particularly dry. Suitable materials can include, for example, thin (preferably about 0.001 inch thick) webs or meshes of polyethylene, polyester, polypropylene, nylon or other heat-bondable fibers, as well as other polyolefins such as copolymers of polypropylene and polyethylene, or of linear low-density polyethylene. Webs are typically composed of micro-perforated film sheet or may be spun, woven, blown, foamed or otherwise fabricated. Composite materials combining, for example, thin non-woven fabric underlying a micro-perforated polymer film sheet or spun net or web can be employed to provide a comfortable, cushioned surface for skin contact. In an alternate embodiment, it is possible for such a composite form of layer 400 to effectively also serve as absorbent layer 350, thereby reducing the number of component layers.

As illustrated in Fig. 16, Fig. 3A and Fig. 3B, cover layer 400 is preferably somewhat wider than layer 350, in order to be folded around the outside of that layer. In this preferred embodiment, cover 400 (when folded) effectively defines the overall width of the sensor portion that is to be disposed inside a diaper. Edges 406 of layer 400 are folded over at the locations of outer phantom lines 412, encompassing the outer edges 354 of layer 350, and continue to the locations of inner phantom lines 414. As shown in Fig. 3B, a portion 416 of the folded edges of layer 400, somewhat smaller than the dimension between phantom lines 412 and 414 (shown in Fig. 16) ultimately covers (by being adhered to) the portion of upper adhesive 304 of impermeable layer 300 that extends outward from edges 316 of openings 310. As previously mentioned, the portions of layer 400 and layer 350 that extend outward beyond edges 308 of layer 300 provide a pair of floating soft edges 418 for the sensor. Portion 416 must not cover the outer-most direct contact portion 356 or the row of openings 310 in layer 300, so that cover layer 400 does not interfere with or provide additional material through which urine must pass in flowing from collecting/spreading layer 350 into the diaper.

The lower adhesive 306 on the bottom of layer 300 helps to maintain the direct capillary contact of absorbent layer 350 with the diaper surface below the sensor, whether through direct contact portion 356 or holes 310, thus facilitating the flow of urine from layer 350 directly into the bulk absorbent layers of the diaper. As can be inferred from Fig. 1 and the side view of the layers in Fig. 4, the exposed portions of bottom adhesive 306 (not indicated explicitly in Fig. 4) of layer 300 are covered by strippable protective portion 112 of layer 110, which is intended to be removed prior to installation of sensor 100 on a diaper. In an alternate embodiment (as can be inferred from Fig. 3B), edges 406 can be folded to encompass layer 300 as well as layer 350, and thus to be adhered instead to portions 309 (outboard of edges 316) on the bottom of layer 300. In such case, portions 309 of lower adhesive 306 would not be available to stick the outer edges of sensor 100 to a diaper, as in the preferred embodiment. As will be apparent to those skilled in the art, the method chosen for combining or attaching cover 400 and layer 350 to layer 300 will depend on the manufacturing economics and relative advantages of using pre-adhesive tape materials versus selectively applying adhesives or of additionally employing other means such as heat bonding. In order to minimize high-volume manufacturing cost, it may well prove generally

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preferable to employ heat bonding or other means, instead of adhesives, for assembly of sensor 100, and to use adhesives primarily for the user-performed attachment and retention applications. In any case, however, it is desirable that the outermost portions of the sensor (except for any floating edges such as 418) be maintained in constant contact with the
 5 diaper surface. This effectively prevents the sensor from becoming uncomfortably bunched or creased inside the diaper. As described previously, it also improves efficient liquid conduction through the sensor. Edge adhesion additionally helps maintain good contact of the exposed portions of the bottom of layer 250 with the diaper surface, thus increasing the sensor's responsiveness to diaper condition.

As illustrated in Fig. 1, Fig. 3, Fig. 3A, and Fig. 16, layer 400 also has a series of elongated openings 410, preferably shaped like and disposed directly above and in communication with elongated openings 252, 330, and 352. These aligned openings offer direct conduits to the upper surfaces of electrically conductive members 202 and 204 for feces-specific detection purposes. In one embodiment, openings 410 are slightly narrower
 15 than openings 252, 330 and 352, or can be merely slits pre-cut through the material of layer 400 in order to provide additional protection against either urine-splash entrance, or direct contact between conductive layer 200 and the skin. The material of layer 400 is preferably sufficiently thin and flexible for openings 410 to be readily moved apart by the presence of feces, thus facilitating the efficient collection and intrusion of such material first through layer
 20 400, and then through aligned openings 352, 330 and 252 and therethrough directly into contact with layer 200 upon elimination. In various embodiments, slits 410 can be adapted into flaps that remain nominally closed when feces are not present. In still other embodiments, somewhat wider openings can be used, or a series of small, possibly non-elongated openings of any shape could serve the function described. Regardless of the
 25 number, shape, or width of openings 410, each such opening must have at least one dimension sufficiently narrow with respect to (e.g., very roughly equal to) the overall depth of the aligned series of openings beneath it (as is determined by measurement of the minimum compressible assembled thickness of layers 400, 350 and 250). Such aspect ratio of the aligned openings effectively eliminates the possibility of a diaper wearer's skin ever being
 30 pressed into openings 410 deeply enough to touch members 202 and 204, and thereby compromise sensor performance -- although such occurrence would not, in any case, be harmful to the wearer.

Functional Summary: Urination-Response in a Preferred-Embodiment Sensor 100

As discussed above (and referring to Fig. 2B and Fig. 3B), urine that is produced by
 35 the wearer of a sensor-equipped diaper is most likely to impinge on, and can readily pass through, cover layer 400 into absorbent layer 350. Layer 350's permeable, flow-collecting and lateral spreading material, preferably bounded at its bottom by adhesive contact with impermeable layer 300, can itself absorb small discharges of urine, while the top surface of
 40 cover layer 400 remains essentially dry. Higher volumes of urine rapidly spread throughout layer 350, and inevitably outward, where portion 356 (or in the alternate embodiment "spillway" openings 310) facilitate direct passage into the diaper. (Still higher rates of flow

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are easily accommodated over side edges 354 and 105.) The direct contact portions 258/358 (or second series of "flow-splitting" openings 320) through layer 300 provides direct capillary contact for liquid transfer between absorbent layers 350 and 250, which also facilitate through-flow of urine into the diaper until such time as the diaper surface's absorbent properties become significantly degraded, relative to those of lower absorbent layer 250. When this occurs (or, in an alternate embodiment, after sufficient delay or after sufficient flow volume) urine can also be conducted towards channel 160 between conductive members 202 and 204, to bridge the gap therebetween, thus triggering releaseably connected monitor/alarm 500 at a time when the diaper's surface absorbent capabilities becomes significantly reduced, either due to total accumulation of urine, or to significantly high rate of urine flow (or optionally after a desired delay time). The capillary trap nature of channel 160 serves to "latch" such a triggered condition for an extended period (up to many hours).

15 **Functional Summary: Defecation-Response in a Preferred-Embodiment Sensor 100**

As discussed previously (and referring to Fig. 2B and Fig. 3A), sensor 100 responds selectively, yet immediately, to the presence of virtually any significant deposition of feces into a diaper. This response is distinctly different from the sensor's urination-related response as described above. Fecal matter deposited on the top surface of the sensor-equipped diaper is collected by means of the inevitable intrusion of such material into and through the sensor's aligned series of shallow, strategically disposed, elongated feces-specific detection openings 410, 352, 330 and 252, to directly contact and bridge conductive elements 202 and 204, which are connected to monitor unit 500. The diaper wearer's skin cannot penetrate these openings, because of the narrow gaps or nominally-closed slit-like elongated openings employed, relative to their depth. (Details of the electronic methods employed in monitor/alarm unit 500, to reliably detect even small quantities of low-conductivity fecal matter, shall be fully described with respect to the monitor unit later in the specification.) The described feces-specific detection structure and means employed by sensor 10 are specific to fecal matter, i.e., they do not compromise the previously-described urination-response, for two main reasons. Firstly, as previously described, the capillary flow properties of these aligned feces openings in the sensor effectively preclude the indirect seepage of urine from the upper absorbent layer 350 and through these openings to reach elements 202 and 204. Secondly, direct streams of urine are physically unlikely to target these openings, due to inherent physiological limitations on the origin and direction of such streams emanating from the wearer, relative to the disposition of the feces openings of the sensor. The relative location of these openings are disposed advantageously posterior (even if close) to the most likely position of the diaper-wearer's perineal mid-line, to function as intended with both males and females.

40 **Adjustment of the Composite Response of Sensor 100 to Reflect User Criteria**

As previously described, adjustment of sensor response to correctly reflect traditional criteria for diaper-changing may be easily accomplished by means of altering the absolute

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and/or relative dimensions of the components, and/or selecting materials with varying absorbency and flow properties, and/or by selectively using adhesives or other bounding coatings on appropriate surfaces (or portions of surfaces) of the various layers to control the relative rate of liquid surface absorbency or liquid loss out of a layer vs. lateral spreading flow rate within that layer, or to control the time delay of flow to a detecting means as will be appreciated by those skilled in the art, particularly in view of the present specification.

The Releasable Electronic Coupling and Retention Portion

As shown in Fig. 2A, sensor 100 extends forward, inside a correspondingly-sized diaper, from a point somewhat below the back "rim" up and over the front rim, where the layer structure is different from the "in-diaper" portion previously described. A proximal end 340 of layer 300 extends beyond fold-line 342 (also shown in Fig. 3, Fig. 4 and Fig. 5A). As previously defined, this line indicates approximately where the sensor is to be folded over and affixed to the outside diaper portion 474. Once applied to portion 474, the sensor is designed to conveniently align with, connect to, and securely retain electronic monitor/alarm 500 (as shown in Fig. 2B). The unique attachment of the monitor unit by portion 450 ensures that, in the use environment, it is typically difficult (and therefore unlikely) for the monitor to be removed or have its operation compromised by the diaper-wearer. It is also designed, however, to facilitate easy removal of the monitor by a caregiver after the diaper is soiled, so it can be applied to the next diaper.

As illustrated in Fig. 5A, the proximal ends of conductive members 202 and 204, supported on portion 162 of layer 150 and tab 166 (and thereby comprising connector tab 170), are accessible where they extend past proximal end 340 of layer 300. At end 340, tab 170 preferably protrudes upward at an angle away from connecting and attaching layer 452 (shown in Fig. 3, Fig. 3C, Fig. 4, Fig. 5A, Fig. 5B and Fig. 7).

Layer 452 is made of thin, preferably impermeable material, and functions to connect layer 300 to monitor-retaining flap 460. This flap is essentially an extension of layer 300, which is provided for purposes of wrapping and retaining the monitor unit. Layer 452 is provided with top 454 and bottom 456 adhesive means. Bottom adhesive 456 is covered (before installation on a diaper) by the proximal part of removable strip 112 of protective packaging layer 110. (Layer 110 is not shown in Fig. 3 or Fig. 5A, but it is shown in Fig. 1 and Fig. 4.) Layer 452 can preferably be a double-sticky tape with a center core 453 of thin (approximately 0.001 to 0.003 inch thick) sheet paper or plastic like polyethylene, polyester or other suitable substrate material such as used for layer 300. The adhesive means can similarly include brushed, rolled or printed-on adhesives, heat melting, or ultrasonic, laser or other bonding processes to eliminate possible cost and other issues related to the use of pre-sticky tapes. Bottom adhesive 456 is provided to affix sensor 100 (and also indirectly, monitor unit 500) to portion 474 of a diaper. (This area is typically already plastic-coated on most brands of diapers for adhesion of the side-closure tapes, flaps or tabs, etc.)

Flap 460 is formed of a thin, preferably somewhat elastically stretchable, and transparent or translucent material. This combination of properties facilitates wrapping, and thereby retaining, monitor/alarm 500 on diaper portion 474, while permitting transmission of

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visual and/or audible alarm signals. Flap 460 is preferably made from clear, or translucent vinyl (about 0.001-0.003 inch thick), although other plastics like polyethylene or irradiated PVC (such as "shrink-wrap"), or even materials such as woven or non-woven natural or synthetic fabric could be used, provided the selected material has the necessary optical, acoustic and elastic properties, and is compatible with the adhesive means employed. In use, flap 460 is ultimately wrapped completely around monitor unit 500 from under its back side, over the front and top of the unit, and is then affixed to the exposed upper adhesive 304 of layer 300 (as can be inferred from Fig. 2B and Fig. 5A and is shown in Fig. 5B). Thus, flap 460 is adhered to layer 452, which is in turn adhered as an extension of impermeable layer 300 for affixing portion 450 to the outside front of a diaper (as previously mentioned). The location of layer 460, vis-à-vis impermeable layer 300 and connective/adhesive layer 452, can be adjusted to facilitate production assembly of the sensor, depending upon whether adhesive is selectively applied to components during the manufacturing process, or if pre-adhesive tape materials are used in conjunction with the application of a non-adhesive layer to create flap 460. Preferably, as shown in Fig. 3 and Fig. 4, the lengths of layers 300 and 460 are adjusted to allow tab portion 170 to protrude through a minimal gap in the otherwise end-to-end junction of these two layers. Disposing flap layer 460 between tab assembly 170 and layer 452 offers the additional advantage of shielding assembly 170 (and also the bottom of the monitor unit when installed) from layer 452's top adhesive 454. In alternate embodiments of the sensor, flap 460 can be fabricated as a continuous extension of layer 300, provided that layer 300 has the necessary properties, as previously mentioned. Also, upper and lower adhesives 304 and 306 of layer 300 would then need to be selectively applied from the distal end, to somewhat beyond fold line 342, so the flap end portion would not be sticky. If layer 300 and flap 460 are combined as the same continuous piece, a suitable opening 344 in layer 300, as shown at location "(344)" in Fig. 5A, can be punched to provide the necessary path to make connector tab portion 170 accessible for connection with monitor 500.

As shown in Fig. 5B, the most proximal end 462 of flap 460 preferably protrudes beyond the proximal (and non-sticky) end of layer 400 to serve as a small pull-tab portion 463 for releasing monitor/alarm 500 from sensor 100 when changing the diaper. The proximal end of layer 400 is fastened to upper adhesive 304 of layer 300, creating a smooth transition. The location and size of portion 463, vis-à-vis the preferably strong adhesive bonds that hold flap 460 to exposed top adhesive 304 of layer 300, and also that hold bottom adhesive 456 of layer 452 to diaper portion 474, ensure that tab 463 is, as mentioned previously, particularly awkward and difficult for a diaper-wearer to remove, yet is easily manageable by a caregiver. As shown in Fig. 22F, in another preferred embodiment, flap 460 is of sufficient length 463-A to extend over the waistband of the diaper (i.e., back beyond fold line 342) to be affixed inside the waistband, further removing the pull-tab from reach of the diaper wearer and providing additional shielding from foreign matter that may be dropped onto the system from above. The flap 460 may also be adhered via separated adhesive portions 475-A disposed towards both edges of the flap, leaving an unadhered central portion of flap 460 providing room for the insertion of a caregiver's finger to facilitate

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removal, while remaining relatively inaccessible to the diaper-wearer.

In various embodiments of sensor 100, either of lower 250 or upper 350 porous layers can also protrude proximally over fold line 342, to provide a more cushioned and comfortable edge (to the diaper-wearer), and to minimize bending stresses on the conductive layer 200. Any such protrusion should be slightly less than that of layer 400, so that the proximal edge of layer 400 is still fastened to upper adhesive 304 of layer 300.

A locating block 470 of foam or other light, rigid material (e.g., 0.125 inch thick urethane foam as shown in Fig. 5A and Fig. 9), corresponds in size to a mating "ridge-like" feature 520 on the bottom of monitor alarm 500 (as is shown in Fig. 18C and Fig. 20). In a preferred embodiment (as shown in Fig. 22F) the locating block tapers inward towards the proximal end of sensor 100 (as does the corresponding portion 520 of the monitor alarm 500) to facilitate assembly in place, providing a guide for ease of initial placement and engagement. Thus, a caregiver can easily tell when the monitor alarm is fully in place. Alternatively, to the extent not fully joined with tab 170, the elasticity of flap 460 will tend to urge the sensor 100 and monitor alarm 500 into more secure and precise connection. Locating block 470 is optionally disposed on the surface of flap 460, where it is affixed by any suitable means such as adhesive, or by other means like solvent, ultrasonic or heat-bonding. The locating block can be provided with a notch 472, which allows connector tab portion 170 to more freely protrude from the rest of the sensor, and thus facilitates insertion of the tab portion by a caregiver into receiving portion 600 of monitor 500. Locating block 470 and mating feature 520 on the back of the monitor unit serve to keep the unit from sliding around on surface 474, and particularly from sliding out of the open sides of the loop created by wrapping retainer flap 460.

The above described locating features can also be replaced by other mating, interlocking, friction-increasing or relative movement-minimizing means. Such means can include a friction pad, or one or more short post-like or ridge-like, preferably rounded or tapered projections on the back surface of the monitor case. These projections can be designed to fit into suitable holes or openings through flap 460 and layer 452. Such projections can be more easily engaged with the sensor if they have tapered or rounded profiles. They can then easily be aligned with the openings and pressed slightly through the sensor into front surface 474 of the diaper. Such appropriately slight indentations are typically unnoticeable to the diaper-wearer. This alternative offers the advantages of eliminating the cost of locating block 470 and also of reducing the total installed height of the retained monitor on the front of a diaper (which is slightly increased by the thickness of the block). In use by a caregiver, the full insertion of connector tab assembly 170 into monitor 500 automatically aligns the monitor properly to be gently pressed down into or onto the provided locating features, as flap 460 is stretched around the monitor and affixed to the front of the diaper/sensor.

The functions of the locating features previously described can instead be served solely by the mating of sensor connector tab portion 170 with corresponding connector receiving portion 600 of monitor 500. In various embodiments, the proximal end of connector tab 170 can be designed to "bottom out" in the end of portion 600, rather than to

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remain "free-floating" as flap 460 is stretched over monitor 500 and adhered in place, thus locating and, vis-à-vis the flap portion, retaining the monitor on the front of the diaper. Particularly if tab 170 is the only locating feature employed, the side walls of receiving portion 600 must have sufficiently small clearance (preferably about 0.025" or less) with the edges of connector tab 170. Also, the tab must have enough rigidity to effectively stop the longitudinal movement of the monitor (when flap 460 is stretched over it) -- as well as to locate and securely retain the monitor laterally. This is particularly practical if the nominal widths of the receiving portion 600 and the tab assembly 170 are made wide enough (such as about 0.75-inch, in the preferred embodiments shown). In such case where the connector tab also serves to solely locate and help retain the monitor unit, the receiving portion of the monitor case and/or the tab portion can preferably have tapering width, so that the sensor tab portion can be readily inserted into the monitor, yet guides itself into place with minimal side clearances as the tab is fully engaged. This arrangement, while eliminating the cost of the locating block, could tend to increase the scrubbing of the conductive elements 202 and 204 against contacts 620, 622 and 624 in the monitor unit receiving portion, due to greater relative movement of the monitor case and sensor tab in the use environment. Some such movement is likely advantageous for at least some choices of conductive elements 202 and 204. With metallic foil conductors, this would tend to promote increased self-cleaning of the contact surfaces. Such movement should be minimized, however, if more fragile printed-on conductive materials are used, to avoid possible loss of electrical contact. Printed conductive materials offer the potential advantage of allowing the contact spacing of layer 200 to easily be made wider only at the connector end, thereby eliminating the need for proximal-end narrowing 162 of double-sticky layer 150. (As previously mentioned, the narrowed portion 162 is employed in the embodiment shown in Fig. 3, to prevent adhesive exposure on either side of conductors 202 and 204 on the top of tab 170.)

As described, tab assembly 170 is designed to protrude either through or, in the preferred embodiment as shown in Fig. 5A, around end 340 of layer 300. This design serves to get conductive strips 202 and 204 from their flow-baffled, capillary-trap functional position (under layer 300 inside the diaper) through the substrate layer to the top side of the sensor portion outside the diaper for connection to the monitor. With this arrangement (as shown in Fig. 5B and Fig. 20), tab assembly 170 (with its conductive strips on top) can be simply inserted into monitor receiving portion 600, where it is pressed upward by a preferably removable spring clip/plate 610 (or other pressure-producing means) against fixed, smooth connector contacts in the monitor case. This simplifies the liquid-sealed connection of these contacts to electronic circuit 900 inside the monitor, and it also facilitates the ruggedness and cleanability of the monitor unit. As will be apparent to those skilled in the art, this arrangement is preferable to having monitor unit contacts address conductors on the outside of a tab assembly (i.e., facing away from the monitor). As previously discussed, alternate embodiments of the sensor could attach the conductive strips to (or make them part of) the bottom of layer 300 or 250, with either feed-through connections to the top surface (for contact pads on the top) -- or a half-twist could be employed in layer 300 or other substrate, to get the front end of the strips on the top surface of a connector tab

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assembly. Any such alternatives would, however, likely increase cost and add other manufacturing and reliability problems. Another solution, with sensor configurations where the conductors exit the diaper on the back side of a contact tab assembly, is to have this assembly enter the monitor from the bottom, as will be further illustrated in the section, "Alternate Embodiments of Portion 450," later in the specification.

Stiffening tab 166 is preferably laminated on the bottom of the sandwich of layers comprising connector tab 170, so that the pressure-spring 610 or other means of the monitor connector slides smoothly and safely against this relatively hard, slippery surface, without risk of scratching or tearing the connector conductive strips (which may be very thin or simply printed-on). This feature also facilitates easy insertion of tab 170 into the monitor, as will be further described with reference to unit 500. On the top side of assembly 170, the contact strips are preferably separated from tab 166 by the top adhesive 154 and/or somewhat soft, compressible material of layer 150, as is shown in Fig. 20. This allows the contact areas of conductive strips 202 and 204 to "pocket" themselves or "cold-flow" over the smooth (preferably rounded) bumps or heads of contacts 620, 622 and 624 in the monitor unit, thereby increasing the reliability of the respective connections.

Alternate Embodiments of Portion 450

Fig. 22A shows an alternate embodiment of the monitoring system, wherein the sensor is incorporated directly into a diaper, and where connecting, locating, and retaining means 450 are implemented very similarly to the add-on embodiment of Fig. 2B. In this case, however, flap portion 460 (and/or optionally other layers like 300 or components such as tab assembly 170) emerge from within the top edge seam of the diaper layers (instead of being folded over from the inside surface) as shown at fold line 342. Just as in Fig. 2B, portion 450 continues down the front of the diaper under the monitor unit 500, in which area part of flap 460 is preferably adhered to diaper portion 474, or affixed by other means. The flap is then wrapped or stretched out and over the front of the monitor to be preferably adhered (by means of suitable strippable adhesive, or affixed by other means) to the top front sensor portion (or to the diaper itself, in still other embodiments where a diaper surface may be suitably exposed).

In the above, or other variations of portion 450, connector tab 170, and also optional locating features (such as block 470, not visible in Fig. 22A under the monitor and flap) position the monitor on the front surface of the diaper, while the somewhat elastic flap actually retains it. Elasticity in flap 460 is not absolutely necessary, as a shallow channel or flap-guiding ridges or other locating features can be added to the front or other surfaces of monitor 500 to prevent lateral slippage out the side of the flap. Elasticity, however, provides a smoother covering and more motion-tolerant, and hence secure, retention of the monitor. Moreover, additional projections disposed on the monitor could result in reduced cleanability and may be less comfortable to a wearer. An elastic flap also makes application of the monitor easier and more convenient for a caregiver. The flap is simply pulled over the monitor to quickly secure it to the diaper.

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It is also possible, in various alternate embodiments of portion 450, for tab 170 or components to exit from the front of a diaper, instead of from the top front diaper seam. Such arrangement may prove desirable for manufacturing, but would appear relatively complex and possibly also prone to leakage. The alternative disposition of a diaper-monitoring unit on the back side of a diaper, while possible, is undesirable for ease of monitor attachment, caregiver convenience, and diaper-wearer comfort and health reasons, including those related to preferred sleeping positions. Various authorities recommend that, for prevention of S.I.D.S. ("sudden infant death syndrome") infants not be encouraged to sleep in a "face-down" position.

Fig. 22B, Fig. 22C and Fig. 22D show various alternate embodiments of connecting, locating and retaining means 450 that can be employed where the sensor is pre-incorporated directly into a diaper, and where flap-like front portion 460 is shorter than in **Fig. 22A**, because it does not wrap entirely around monitor/alarm 500 on the front of the diaper. Instead, locating block 470, which helps position the monitor, is separately disposed on the front of the diaper, and the flap wraps in a downward direction over the monitor unit, to retain it over the locating block. In order to avoid the tendency for tab 170 to be pulled out of the monitor by the action of stretching the retaining flap over the unit (as can occur with the arrangement shown in **Fig. 22B**, particularly if a locating block is not used), the sensor tab can preferably enter the monitor from the opposite, or bottom end, relative to the embodiments of **Fig. 22A** and **Fig. 22B**, as shown in **Fig. 22C**. Note, however, that in this case the proximal ends of conductive contacting elements 202 and 204 of tab 170 must be on the opposite (or bottom) side of the tab to mate with a different monitor configuration (shown in **Fig. 21A**) wherein connector opening 600 is at the bottom of the monitor unit. This requirement for the conductive contacts to be on the bottom of tab 170 may be satisfied by the use of certain alternate sensor embodiments as previously discussed with reference to eliminating layer 150. Alternatively, it can be satisfied by a half-twist in the connector tab assembly or by other means, as will be apparent to those skilled in the art. An entirely different approach can employ an alternative "edge-clip" monitor connector embodiment as shown in **Fig. 21B**, so that strips 202 and 204 can be on the top side of tab 170, even with the connector assembly disposed on the bottom end of the monitor. Such monitor configuration would then be used in conjunction with the sensor shown in **Fig. 22D**, where the proximal end portion of tab 170 may preferably be bent to project relatively more sharply outward from portion 474. As will be appreciated by those skilled in the art, the above the methods illustrated in **Fig. 22B, Fig. 22C and Fig. 22D**, for the implementation of portion 450, can be applied in various combinations and also used with diaper add-on embodiments as well as incorporated ones.

Fig. 22E shows how, in embodiments where the sensor is built-in to a diaper, flap 460 and any monitor-locating features (other than tab 170) can be entirely separate from the rest of the added sensor components and can be either affixed to, or integrated with the front of the diaper as shown at 474. Such an alternate embodiment may well be most advantageous for manufacturing when the sensor is built-in to diapers, because it eliminates the complexity of getting tab 170 from the bottom through or between other layers of the

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sensor. Moreover, this method eliminates the need to join sensor-substrate layer 300 to flap 460 in the manufacturing process, thus facilitating the use of different materials (such as "double-sticky" tape for 300 but not 460) in separate continuous-strip processes, and/or simplifying the disposition of adhesives on only the appropriate portions of a single component. This approach (Fig. 22E) also avoids extending tab 170 as shown in Fig. 22C and Fig. 22D.

The embodiment shown in Fig. 22E also retains the most preferred "upward-wrapping" direction of flap 460 over the monitor unit, as shown in Fig. 2 and Fig. 22A, which arrangement offers the best caregiver visibility when attaching the monitor to a diaper/sensor, as well as making the removal of flap 460 (at the time of diaper changing) more convenient. As shown in Fig. 22E, only tab 170, as well as optionally a short extension of layer 300 and cover 400 (to provide a smoothly finished fold-line edge), need continue forward from the "in-diaper" sensing portion, to emerge from the top edge of the diaper (where they most easily exit the laminated diaper layers) to reach the front monitor location without creating a possible leakage path. Retaining flap 460 and optional locating block 470 can likely be more easily fabricated and affixed to (or integrated with) the front of the diaper if they are not part of the in-diaper portion of the sensor assembly. Flap 460 can thus be wrapped (preferably stretched) around unit 500, to then be adhered to the exposed adhesive on the proximal extension of layer 300 (or otherwise attached).

In any of the previously described embodiments of portion 450, suitable releasable attaching means (such as adhesive) can alternatively be disposed on the proximal portion of flap 460, near end 462, for the purpose of securing the flap after it is stretched over the monitor. In those cases where the flap wraps downward over the front of the monitor, adhesive can be used at the bottom of portion 474, as indicated on both flap 460 and the diaper in Fig. 22B, Fig. 22C and Fig. 22D. In any of these cases, a variation of strippable, top cover sheet 455 (as shown in Fig. 2A and Fig. 17) can protect the exposed adhesive prior to the attachment of monitor 500.

Monitor/Alarm Unit 500

As illustrated in Fig. 18A, Fig. 18B, Fig. 18C and Fig. 18D, monitor/alarm 500 includes a protective case 510 having an upper portion 512 and a lower portion 514. Lower portion 514 has raised ridge or collar portion 520 that serves as a receptacle for locating block 470. As was previously described with respect to sensor 100, various other forms of mating, interlocking or friction-producing features or materials could be employed in the sensor and/or monitor unit to accomplish the purpose of positioning and laterally retaining the monitor unit with respect to the surface of the disposable sensor and diaper. Lower portion 514 has a preferably recessed receiving portion 600. Together with spring clip/plate 610 and contact pins 620, 622 and 624, portion 600 helps provides monitor 500 with reliable electrical connection to the sensor, and also contributes to the proper location and secure retention of the monitor. Upper portion 512 provides a top, relatively smooth surface for the location of a faceplate overlay 517, which optionally includes design graphics 518 such as a "balloon" or other design. Overlay 517 comprises a functionally integral part of a mode

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change assembly 700, a visible signal transmission assembly 750, and an audible signal assembly 800. Upper and lower portions 512 and 514 each also provide their respective halves of a top 530, a bottom 532, a left side 534 and a right side 536 of case 510. Disposed within case 510 are a circuit board assembly 910 with a lithium coin-cell type battery (BTY), an audible transducer BPR (elsewhere referred to as 810), a visible display LED, a mode-change switch S1 and sensor-tab contacts 620, 622 and 624, altogether comprising the monitor/alarm portion of electronic circuit 900 as depicted in the block schematic diagram of Fig. 23. The upper and lower portions of case 510 are preferably joined to form a permanently-waterproof sealed case, which is designed to require no opening for repair or battery replacement during its intended useful life.

Sensor-Connector Receiving Portion 600

Receiving portion 600, as illustrated in Fig. 18B, Fig. 20 and Fig. 21A, receives tab 170, when inserted between a first 612, a second 614 and a third 616 set of prongs of spring clip/plate 610, and contact pins 620, 622 and 624, respectively. Contact pin 624 receives narrower conductive member 204. Contact pins 620 and 622 both receive wider conductive member 202, thereby completing the monitor circuit between pins 620 and 622. This action switches-on monitor 500 automatically, upon insertion of tab 170 (as will be further discussed with respect to monitor circuit 900). In a preferred embodiment (as shown in Fig. 20), there is provided a greater protrusion of contact pins 620 and 624, relative to center pin 622, from the upper surface of portion 600. The pressure of spring prong 614, in directly forcing the center of tab 170 against pin 622, acts in conjunction with the difference in protrusion of the contact pins, to gradually cause flexion of the resilient tab/conductive strip assembly as it is inserted. This arrangement thereby ensures the constant pressure of conductive strips 202 and 204, on tab 170, against each of the contact pins. This flexion of tab 170 also increase the frictional force by which the tab is retained in recess 600. A smooth rounded tip 619 of spring prong 614 preferably protrudes slightly (at an angle away from portion 600) beyond case top surface 530. Tab 170 is initially guided into place by tip 619, the edges 612 and 616 of plate 610, and also is centered and aligned by the sides of recess 600 in the monitor case.

In other words, to create a reliable connection for all monitor contacts, the preferably narrow cantilever spring prong 614 presses the axial mid-line of the tab directly against the center of three spaced contacts (or the top of the recess in the monitor case if only two sensing contacts are used). Because two outboard contact "bumps" 620 and 624 protrude relatively farther than does center contact bump 622 (or the monitor-case surface if only two contacts are used) the spring clip also causes the resilient contact tab itself to flex and act as a flat-spring element. This second spring force acts to securely press the conductive elements of the tab assembly against the outer contacts. (The relative protrusion of contacts could alternatively be reversed or mirrored, i.e., center-high and sides-low to achieve substantially the same purpose.) Because any subsequent relative motion of the connector tab and monitor simply "scrubs" the conductive strips over the smooth surface of the contact bumps while the contacting surfaces are under continuous pressure, self-

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cleaning and reliable electrical connection is assured.

With the preferred three-contact arrangement as described above, the monitor unit's operation is automatically turned-on (from a zero power-consumption state) at the same time and by the same means that connection is made between a disposable sensor and the reusable monitor unit -- by simply inserting tab 170 into slot 600.

The retaining and contacting forces described above can optionally be made "field-adjustable" by the variable tightening of an attachment means 618 (preferably a screw), which can be employed to hold spring clip/plate 610 in place on lower portion 514 as shown in **Fig. 18C**. Whether adjustable or not, the use of a screw or other removable attachment of spring clip/plate 610 readily allows its replacement, should it become weakened or damaged. It also facilitates the occasional cleaning of recess 600 and its connector contacts, as may become necessary in the use environment, by making this otherwise enclosed area of the monitor readily accessible. Alternatively, spring clip/plate 610 can be slid into molded-in "dovetail" or other type slots in the monitor unit case and further located and retained by friction, or by a molded tab/detent or other means. Spring clip/plate 610 is preferably made of thin, corrosion-resistant sheet material (e.g. 0.015 inch thick, stainless steel or a likely thicker, suitable engineering polymer or composite).

Spring clip/plate 610 covers and thereby physically protects the contact area of the monitor, and also ensures that the connector tab of the sensor remains aligned with respect to the contact pins. The narrow (e.g., 0.125-inch wide), cantilever spring prong 614 preferably has no electrical function, but initially guides the tab as it is inserted into the slot between plate 610 and recess 600.

Tab 170 and mating slot recess 610/600 in the monitor unit are sized such that, when inserted, the end of the tab reaches lengthwise well past the contact bumps, but preferably does not reach the end of the slot (thus ensuring that the monitor unit will be positioned by locating block 470, or other locating feature, regardless of the exact end position of the tab). This arrangement (as previously mentioned with respect to sensor 100) minimizes the relative scrubbing of the sensor tab conductive elements against the connector pins which could otherwise compromise the electrical reliability of the connector during use. The width of slot 600 is only slightly wider (preferably about 0.050 inch) than connector tab 170, to ensure continuous alignment of the conductive strips and contact bumps, while still allowing easy insertion. The three entrance edges of slot recess 600 in the case are smoothly radiused, and the contact bumps are rounded and slightly countersunk into their respective locations in the monitor unit case. These features allow the connector tab a smooth ramping entry into the slot (without encountering edges of the contact bumps) as it is flexed by the spring and bumps. To make the initial engagement of tab 170 into slot 600 as easy as possible for a caregiver (and as previously mentioned), tip 619 protrudes a short distance beyond top edge 530 of the case, so as to automatically "catch" or capture the end of the tab into slot 610/600 as the monitor is applied to a sensor. Top edge 530 of the monitor case may preferably have contrasting marking or may be slightly recessed or ridged (as shown at 516 in **Fig. 18A** and **Fig. 18B**), to highlight (to a caregiver, viewing from above) exactly where tab 170 should be inserted. As previously described with reference to

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sensor 100, the material properties and order of the layers comprising tab 170 enhance both the ease of tab insertion/removal and also the contact- retention and reliability achieved by the connector means of the system.

The sensor-connection and monitor-retention means as described above employs fully liquid-sealed electrical connection directly through monitor case portion 514 at the bottom of recess 600 (and therethrough to an electronic circuit board assembly 910 inside), by contact bumps 620, 622 and 624. These bumps, in a preferred embodiment, are corrosion-resistant metal pins (e.g., stainless steel or gold or nickel plated brass) with smoothly rounded heads.

An alternative embodiment of receiving portion 600, shown in **Fig. 26A**, employs a preferably molded channel 600 in back case portion 514, the channel having three smooth-headed contact pins or bumps 620, 622 and 624, disposed on its surface, with a pair of smooth, preferably tapered or ramping protrusions 636 and 638, disposed on the opposing surface of a pressure-plate 605, which is preferably removable, but rigidly located in relation to channel 600. Plate 605 can be molded as a single piece of plastic and fixed in place by having beveled side edges that slide into dovetail slots in case portion 514 (such as shown at 617), or be held to case portion 514 by a screw, or by other means. Protrusions 636 and 638 are each disposed approximately between middle 622 and outer 620 and 624 contact pins, respectively, to form tab assembly 170 into a waveform, thus insuring contact with each of the contact pins and retention of the tab within the recess 600/605. Pressure plate 605 (with its protrusions 636 and 638 combined with the resilience of tab assembly 170) thus effectively replaces spring clip/plate 610 (of the previously described embodiment) and can preferably have a molded lead-in lip 606 to capture tab 170. Contacts 620, 622 and 624 may protrude to the same or different amounts and may be either symmetrically or asymmetrically placed. Other embodiments include employing different contact members on alternate sides of recess 600 (such as having the equivalents of contacts 620, 622 and 624, but rather with them disposed alternately to address both top and bottom surfaces of a connector tab, such that a circuit therebetween is bridged upon insertion of the assembly for on/off operation without employing wider and narrower contact members, thereby reducing the width of the connector assembly), the attendant modifications of the sensor connection being apparent to those skilled in the art, in light of this specification.

The flexible-tab connector means of the elimination-absorber monitoring system is intended to provide high reliability in this demanding use environment with maximum caregiver convenience – at minimum cost. It may well find other uses, where low cost, high reliability, ruggedness, flexibility and convenience are paramount. For example, many products, systems and devices have need for making motion-tolerant electrical connections between a flexible-circuit element and some other element. The approach employed in monitor 500 eliminates much of the cost and other drawbacks of any add-on connector device which would otherwise need to be attached to a termination-end of a flex-circuit such as tab 170. A small, inexpensive plastic stiffener tab can be bonded to the back of a flex-circuit (e.g., 0.010-inch thick polyester in the case of tab stiffener 166 in sensor 100) to provide the desired contact pressure when used with a suitable spring clip or pressure-

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producing means. (Alternatively, with appropriate choices of material and dimensions, the flex-circuit substrate itself may be resilient enough for this purpose.) The conductive strips of the flex-circuit can be exposed a short distance back from end of the tab by selectively eliminating the top insulating lamination or coating of the flex-circuit in this region, where the conductive strips may optionally be plated or coated with a contact and reliability-enhancing material (such as gold). The whole connector system can easily be made water-resistant and is very simple to clean and maintain. It also has the major advantage of providing reliable, positive, automatic alignment – and extreme ease of repeated connection and disconnection.

The concept of this flex-circuit tab connector can easily be extended to multiple-circuit connections (i.e., more than two or three conductive circuits as used in diaper-monitor 500) by means of simply alternating the relative protrusion-height of the spaced contact bumps in the slot of the “female” part of the connector (such as slot 600 in case portion 532 of monitor 500). As in the two or three-circuit situations, the flexible, resilient, “male” tab which carries the flex-circuit conductors is then “rippled” slightly as it is inserted into the slot, where it assumes a slight “wavy” cross-section where it passes over, and springs against the multiplicity of contact bumps, as further explained below.

Further Discussion Of Alternate Connector Embodiments

As may be inferred from Fig. 26B, regardless of the number of conductors provided, pressure spring 610 of the connector employed in an elimination-absorber monitoring system or in other applications can alternatively be replaced entirely by a series of fixed (preferably molded-in) ramping protrusions or tapered-height pressure bumps (e.g., 636 and 638 shown) rising from the inside of a slot surface opposite to the surface with contact bumps (such as 630, 632 and 634 shown). One embodiment of such bumps can be visualized as lengthwise-bisected ice-cream cones lying on their sliced sides. These bumps are located such that each pressure-bump is spaced midway between an opposing pair of contact bumps (i.e., equally-spaced along their centerline) to gradually force the resilient connector tab into a lengthwise slightly wavy shape as it is inserted into the slot. These pressure bumps are tapered or ramped from zero-height (at the entry of the slot) to a their maximum height at the centerline of the contact bumps.

As shown in Fig. 26B, the contact bumps may themselves also be tapered in height, to minimize insertion force and to aid in deforming the tab. In this configuration (without a pressure spring), all the contact-maintaining force is supplied by the inherent resilience of the male connector tab itself. The surface of either or both the connector bumps and the pressure bumps may preferably be extended into a smooth angled lip 606 (on any of the opening edges of slot 600/605) to make capture and insertion of the male tab easier. With pressure bumps rising out of a (preferably molded) plate (instead of formed pressure spring and integral plate), the contact bumps need be the only conductive (and hence, likely the only metallic) portion of the entire female part of the connector. As previously mentioned, pressure plate 605 which covers recess 600 in the female portion of the connector can easily be made to slide into “dove-tail” slots, or be retained by use of one or more fasteners,

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detents or by any other appropriate means.

A "double sided" form of the connector can be made by changing the "pressure bumps" into conductive "contact bumps" and simply staggering the conductive strips of the flex-circuit tab (i.e., shift the pattern of strips on top and bottom of tab so they are perfectly "mis-registered" top-to-bottom). Either or both sets of connector bumps can be the ends of flex-circuits (or two halves of the same two-layer flex-circuit) leading out of the "female half of the connector. This makes it particularly easy to create "in-line" connections for various other applications, or to bring the connections into another circuit (board) assembly. It is also possible to employ an alternative method, where the conductive strips enter into the female connector to slide and ripple "sideways" over smooth contact bumps, but this has the disadvantage, for some applications, that momentary "wrong" connections can occur as the conductive strips approach their final (intended) registration with the contact bumps. It is also possible to create a "zero-insertion force" connector with either of the orientations by using a cam or other simple mechanical device to separate the contact bumps and pressure bumps (or contacts) for insertion of the connector tab, after which the process is reversed to "clamp" down on and deform the tab into a "wavy shape" as with the ramp-in method above.

The Control and Indication Interface

Monitor unit 500 utilizes a novel, simple control and indication interface with highly intuitive operating procedures. Diaper-monitoring units must be operable by very young baby-sitters, elderly or handicapped caregivers, and in general, any person that may at the time be acting under considerable stress or distraction in virtually any location or situation. For this reason, the present invention provides that the only required caregiver actions (for control purposes during operation of the elimination monitor) consist of "one-handedly" pressing a single switch (as described below with reference to a mode-change assembly 700) to both test and verify proper operation, and also to change alternately between the audible and visual alarm modes. Each pressing of the switch causes the unit to alternately emit either a momentary audible or visual alarm indication, but only if the unit is properly connected to the sensor and the system is ready to monitor a diaper. Each indication (either audible or visual) also clearly confirms the current mode (audible or visual) the monitor is set to operate in. The monitor unit operates continuously, in whichever mode it is set to, as long as a sensor is connected to it, thereby eliminating the possibility of it being accidentally left off or turned off. (The unit consumes no power when a sensor is not connected and conversely, connecting a sensor automatically switches the unit on.) As will be apparent to those skilled in the art, an alternate embodiment of monitor/alarm 500 could provide for both audible and visual alarms to be used together, with the likely consequence of increased power consumption.

The Mode-Change Assembly

Mode-change assembly 700, as shown in Fig. 18A and Fig. 21A, consists of a single waterproof, momentary-type flat-panel switch (S1 shown in the schematic diagram of Fig. 23), covered by a sealed faceplate overlay 517 on front case portion 512 of monitor unit 500

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and is located near a lower corner of the faceplate to make it relatively less accessible to the diaper wearer than to a caregiver. The switch can be of any suitable type (such as the typical miniature dome-type keyboard switch which is used in the preferred embodiment) mounted on the top of the unit's circuit board, at such relative height and position that the

5 the end of its moveable push-button or other such activating button protrudes through a slightly larger hole 705 in the monitor unit front case portion 512. The switch button is nominally flush with the case top surface where it touches the bottom surface of flexible, waterproof, graphic overlay sheet 517, which seals hole 705. (In an alternate embodiment, an activating button protrusion can be molded into the top case surface along with a

10 surrounding annular flexible feature for the purpose of reaching down to a relatively flat type switch below, either with or without the use of a separate flexible overlay.) Overlay 517 is somewhat smaller than the face surface of the monitor and is permanently (and preferably adhesively) affixed to a shallow locating recess in the front case portion 512 during its manufacture. This overlay is preferably a thin (typically 0.001-0.010 inch thick; 0.003 inch

15 thick in the preferred embodiment) flexible rubber or plastic sheet such as vinyl, polyester, or polycarbonate (polyester is used in the preferred embodiment). The properties of the overlay must be selected to provide rugged protection of the switch in the use environment while still allowing the firm, targeted pressure of a caregiver's finger to conveniently and reliably actuate the switch. The pressure required can be preferably tailored by selection of

20 the switch, adjustment of the case through-hole clearance or the end-gap (or preload force on the activating button) between the switch and overlay to make it relatively more difficult for a baby to actuate it. A graphic design on the overlay location (such as a "dot" 702, shown in **Fig. 18A** on overlay 517, directly over hole 705) can also provide indication of the switch's location -- which would otherwise not be apparent -- and can thus be made as

25 obvious or not, as desired. The preferred position of the mode-change switch, when monitor 500 is installed on a diaper for use, is relatively inaccessible to the wearer, and can be made more so.

The top edge of hole 705 in the monitor case should be chamfered or rounded, so that repeated switch activation will not excessively stress overlay 517. The overlay is as thin

30 as possible, consistent with the considerations discussed above, both to prevent flexure-induced fatigue failure, and also to avoid unnecessary attenuation of the audible alarm means of monitor 500 (which communicates via acoustic vibration through the same waterproof overlay). Mode-change switch S1 is connected, via the circuit board on which it is mounted, to the monitor units electronic circuitry wherein it actuates a suitable logic input

35 to effect the changes between the monitor unit's audible and its visual alarm modes.

The Visible Signal Transmission Assembly

A visible signal transmission assembly 750, as shown in **Fig. 18A**, **Fig. 21A**, and **Fig. 27**, is designed to work in conjunction with flap 460 of sensor 100 in order to achieve

40 sufficiently high brightness and useful viewing angle, with sufficiently low power consumption in the use environment. A high-efficiency, high-intensity LED (light-emitting diode) as shown in the schematic diagram of **Fig. 23** is selected to be a "super high brightness" type,

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typically having a focusing lens with a relatively narrow "viewing" or beam "exit-angle" (such as a Mouser Electronics type 351-5200, a T-1 ¾ size red device having specified luminous intensity of 1,200-2,000 mcd at 10 mA, and a 20-degree exit-angle). Such devices having impressively high brightness, but narrow exit-angle output are readily available, but in typical applications they are very hard to see "off-axis", particularly in bright (or direct sunlight, or outdoor) ambient light. The LED is mounted inside monitor unit 500 at such position and relative height that it can project virtually all its light output through a hole 755 in monitor case front portion 512 and then through an aligned, relatively transparent window in any graphic design or other opacity of the unit's thin, adhesively-sealed permanent faceplate overlay 517 (as shown in Fig. 27). The through-hole in the case is provided with a chamfered edge 760 and is suitably dimensioned so that the emerging light cone or exit angle is not obstructed, but the unit's interior is otherwise shielded from view. The emerging focused light cone passes through the transparent window and then impinges on the bottom surface of the preferably translucent portion of sensor flap 460 which is designed to wrap over and to secure the monitor unit in place, while also acting as a light diffusing, rear-projection screen for the LED light cone. The described arrangement ensures that virtually all the LED chip's light output is efficiently transferred to, and suitably diffused over, the desired indicator area of the viewable outer flap surface of the sensor, and also results in practically 180 degrees of viewing angle when the monitor is in use. This arrangement also eliminates the need for any openings in, or accurate alignment of, the covering flap with the monitor unit to avoid obstructing the visual display. In an alternate embodiment, the monitor unit faceplate overlay may have light diffusing properties as well, thereby providing (when shining through the flap) additional angular diffusion or scattering of light, at the expense of some brightness. Faceplate overlay 517 may preferably have graphics integrated with the LED window such as balloon 518 or other attractive icon or design which can be seen through the sensor flap when the monitor unit is attached to diaper. Even if the sensor flap is a strong diffuser of light, the front panel overlay of the monitor unit is still clearly visible through it because the flap is stretched tightly over the unit, holding it in place. In use, the wearer's outer clothing can also act as a rear-projection screen for the LED, through which, rather surprisingly, the visual indications can be easily seen, even in relatively bright light (except in cases of thick, multi-layered, dense or dark-colored clothing materials).

The effective and convenient use of a diaper-monitoring system through clothing worn over the diaper is a significant advantage of the present invention over prior devices -- and particularly over various non-electronic approaches that have all required that such clothing be repeatedly removed, and the outside of the diaper visually inspected -- to determine when the sensor had been activated. The mode change assembly 700 of monitor unit 500 (as previously described) is easily operable, even "one-handed", through clothing. The unit's audible-mode indications can be easily heard from across a room, or even from a distant location via an ordinary remote baby monitor and, as explained above, both the audible and the silent visual-mode indications are effective through outer clothing.

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The Audible Signal Transmission Assembly

An audible signal assembly 800 shown in Fig.18A and Fig. 28, utilizes a specialized portion of sealed faceplate overlay 517 of monitor unit 500 as a passive resonator membrane so that alarm signals (and particularly desirably low frequency ones) can be efficiently transmitted from a low-power, electro-acoustic transducer 810 ("BTY" in the schematic diagrams) to caregivers without compromising the waterproof seal of the unit's case (see Fig. 28). In at least one location, this overlay membrane is uniquely supported (but not normally touched) by features in the unit's case (disposed under the membrane) so that it is protected from damage due to excessive flexure, but its damping is not increased. Moreover, effective transmission of audible alerts through the sealed monitor case is accomplished at minimum cost and visual impact because no additional or noticeable, sealed, acoustically transmissive component is needed, leaving a smooth and easily cleanable surface.

Prior electronic devices, and products of many kinds, have used audible transducers in conjunction with one or more openings in or holes through the respective units' cases to allow sound to emanate -- and have thus not been capable of waterproof integrity. Other prior devices have commonly employed a sealing membrane disposed behind a rigid or semi-rigid protective grille or panel, presenting an outer surface prone to trapping liquid or foreign matter in small openings that are particularly difficult if not impossible to clean. Still other prior devices (particularly waterproof "alarm watches") have relied on conduction of sound through the unit case itself or through a relatively rigid component, such as a watch-face crystal, to address this problem. Because relatively rigid materials do not effectively conduct and then transmit to the air relatively low frequencies of acoustic or mechanical vibrations, this approach limits the usable sound frequencies to rather high pitches which are not desirable in many applications. For example, many people suffer from high frequency hearing loss that prevents them from effectively using such devices. Moreover, higher frequency audible alarm indications can be harder to notice over environmental background noise than are lower frequency sounds. If they are made loud enough -- they can often become annoying in other circumstances. For years, engineers have employed the common prior-art strategy of simply (and often greatly) increasing the signal output power that drives an audible transducer, to overcome the rather severe attenuation of sealed electronic-device enclosures. Unfortunately, this practice has generally significantly limited battery life, by worsening what is inherently one of the most power-consumptive operating aspects of many devices.

In the present invention, a suitable transducer is selected from any of several types including (but not limited to) electro-magnetic buzzers, piezoelectric beepers and loudspeakers. In the preferred embodiment, the transducer is selected to be a relatively small, very low power, electro-acoustic beeper with a desirably low resonant frequency of 2,048 Hz (such as an International Components type BRT-101). It is capable of producing sound pressure levels of about 80 dB(A) at 10 cm. range (in free air), while consuming less than 30 mW (rms) of power. This device itself incorporates a Helmholtz-type resonant enclosure with a small hole 820 at its top (approximately 0.125 inch in diameter). In typical

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electronic products, this hole is positioned behind, and in alignment with, a similar sized through-hole in the product's case. In the present invention, this transducer is driven by the monitor unit circuit which, at suitable times, produces "square-wave" signals having approximately 2.5-3.0 volt amplitude and having frequency approximately equal to the resonant frequency of the transducer (when sealed in the monitor unit's case).

In order to achieve the highest possible transfer-efficiency of acoustic energy from transducer device 810, through the sealed faceplate overlay membrane 517 of monitor unit 500, it is desirable to maximize a relatively undamped, free-flexing "drum head" area of the membrane, relative to its thickness. This is done by providing a relatively large but very shallow recess 830 in the monitor unit's case preferably directly behind the acoustic "passive radiator" or drum head portion of the faceplate overlay (approximately 0.375-inch in diameter and 0.015 deep in the preferred embodiment). The bottom of this recess is preferably molded directly into the upper case section 512 and is perforated with one or more (but preferably a plurality of) openings 540 for relatively unobstructed acoustic transmission, but is still relatively rigid and strong in order to limit the maximum deflection of the membrane to just slightly more than its greatest amplitude when it is vibrated by acoustic compression waves from transducer device 810 inside the unit. This arrangement serves to prevent the overlay membrane from being pushed into the case during handling (or by "probing" on the part of a child or infant) and thus acts to prevent its damage, by limiting the deflection of the overlay material to well within its elastic range. Because the overlay seamlessly covers the recess, the location of the recess can be made visually unnoticeable, further reducing the likelihood of damage to the membrane.

In variations of the preferred embodiment shown in **Fig. 28** with overlay 517 having uniform overlay cross-section, the overlay may instead be laminated from two or more layers of the same or different thicknesses so that an acoustically-active portion lying above the shallow recess (as described above) can be thinner than other areas of the overlay by eliminating adjacent portion(s) of one or more of the other layer(s), thus providing an optimal balance of durability and sound transmission. In one such case, a thin, acoustically-active outermost layer can be disposed above the eliminated adjacent portion(s) of the inner layer(s) such that the eliminated portions taken together with the supporting panel or case itself serve the function of shallow recess 830. Similarly, as described previously, part or parts of the overlay can be relatively transparent for visual display purposes, or have other desirable properties where switches or other devices are located under the overlay.

The enclosure of a transducer device into a relatively small sealed volume, as in the present invention, inherently raises the resonant frequency of the transducer. This fact necessitates that the driving signal have appropriately adjusted frequency for maximum acoustic volume. A transducer's own enclosure (if used) is generally tuned for maximum transfer of acoustic energy to the relatively "infinite" volume of a room or outdoors. In the case of the present invention, however, the case design of the monitor may be modified to provide additionally optimized acoustic impedance matching (i.e., coupling) to the overlay membrane. The transducer device or its own resonant enclosure may also be suitably modified to achieve the same purposes as will be readily apparent to those skilled in the art.

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Moreover, the monitor case can be partially evacuated of air, and/or filled with a suitable gas to reduce the cavity resonant frequency or the acoustic damping produced by the small internal volume of the case to enhance the efficiency of acoustic transfer. The partial evacuation or filling of the monitor unit case with relatively inert gas can also be used either with or without solid or jell-type potting or conformal coating to prevent deterioration of the monitor's internal components due to corrosion or other chemical effects.

Other Applications of the Audible 800 and Visible 750 Signal Transmission Means

It will be apparent to those skilled in the relevant arts that the basic elements of both this invention's audible and visible signal assemblies are also applicable to other diverse applications using non-audible or non-visible wavelengths (such as ultrasonic/infrasonic or infrared/ultraviolet waves, respectively). It will also be apparent that these methods are symmetrically applicable to situations wherein the respective transducer is either alternatively or additionally a detector of the signals, with a given "acceptance-angle" instead of purely a source with a given "exit-angle". Most, if not all the respective advantages cited for these methods clearly apply to such other applications.

The Electronic Methods Employed by Monitor 500

As illustrated in Fig. 23, the monitor/alarm circuitry 900 preferably employs narrow, relatively fast transition-time pulses generated by an oscillator circuit for conductivity measurement, instead of either the DC or sinusoidal AC methods employed by previous systems. The pulses can have a duration of about 0.1 second and a repetition rate of about one pulse every 3 seconds. This rate is chosen as a compromise between the "see-it-at-one-glance" user preference (as determined by subjective testing with selected caregivers who typically did not like to wait more than 3-seconds while watching for an alarm flash to occur) and excessive power consumption caused by more frequent alarm indications (assuming that the same pulse widths and repetition rates are used for both sensing and alarm indication). Alternatively, as discussed below, the pulses can preferably be doubled, i.e., each burst comprising two pulses, each having a duration of about 0.1 second, separated by about 0.1 second off-time and such bursts occurring about every 3 seconds. This relatively low duty-cycle offers the advantage of allowing the ions in the matter being monitored to recover their normal, random distribution between pulses, so that the average measured conductivity does not radically change over time. As may be appreciated by those skilled in the electronics art, different embodiments of monitor circuit 900 could instead apply pulses to the sensor that alternate in polarity, or the pulses could be applied through (i.e., in series with) a capacitor to achieve a true zero time-average of applied voltage. Such alternative methods are, however, more component-intensive and complicate, if not preclude, the integral automatic power-switching via connection of sensor 100. The high-frequency harmonic-content of the pulse waveform, due to the fast transition-time of the pulses, also exploits a phenomenon commonly referred to as "skin conductivity" of solids, whereby relatively higher frequency electrical signals often travel much more easily over the surface of solids and semi-solids than do lower-frequency or DC signals. This

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phenomena is particularly useful for reliable feces-sensing. Moreover, digital switching in the oscillator circuit that generates the pulses is much more energy efficient than can be achieved with AC sinusoidal oscillators, resulting in longer battery life for monitor/alarm 500.

The same pulse widths that are generated for sensing are, in one preferred embodiment (as shown in the schematic diagram **Fig. 23**), also used for the beeps or flashes produced by the monitor unit to indicate the "diaper needs changing" state, permitting the combination of electronic functions and facilitating further energy savings. In various microcontroller-based embodiments (as shown in **Fig. 24A**, **Fig. 24B**, **Fig. 24C** and **Fig. 24D**), it is alternatively feasible to have different pulse widths and/or repetition rates for sensing as are used for alarm indications, without increasing the component count. Such an embodiment can use very narrow pulses for sensing (typically a few milliseconds wide) to minimize both power consumption and ionic dissociation. As mentioned previously, in order to optimize the observability of the alarm signals (particularly in the face of competing background noise or ambient light) it is preferred to use double (or multiple) pulses rather than single pulses for alarm indication. Alternatively, other types of audible and visual signals can be employed, such as musical tunes, simulated animal noises or other sounds, as well as voice or displayed messages. Such alternatives, however, are likely to result in more complex circuitry, increased power consumption and potentially greater size and weight.

Preferred Discrete-Logic Embodiment of Electronic Circuit 900

Referring to the electronic circuit diagram (**Fig. 23**) of a preferred discrete-logic implementation of monitor unit 500 and connected disposable sensor 100, a combination of CMOS logic gates (such as the 4000-series or 74HC-series devices) and other standard components provides all the necessary electronic functions. Several functional blocks which can be implemented using common methods are shown simplified for clarity. For example, a low-frequency CMOS "double-pulse oscillator" block (U7) generates a continuous waveform, as shown, whenever the unit is connected to a disposable sensor, thereby providing the primary timebase and conductivity-measurement pulses for the monitor circuit as well as pulses for audible or visual alarm activation. As will be readily apparent to those skilled in the electronics art, this type of oscillator block can be implemented using a number of common techniques, including simple R/C relaxation oscillator configurations with suitable standard gates. Although various types of crystal or ceramic resonator oscillators could alternatively be used, timing accuracy greater than about $\pm 10\%$ is not necessary in this application and the simple R/C oscillator approach is generally the most economical. Typical CMOS gates with negligible output loading provide output swings essentially from 0-V to +V as well as having relatively fast switching transition times in the microsecond range or faster, which are desirable both for power minimization and for effective measurement of feces-related conductivity.

The double pulses produced by U7 are applied through sensing reference resistor R2 (preferably about 2 megOhm in a preferred embodiment) to sensor-connector SC1 (same as contact pin 624) and thereby to conductive strip 204 of disposable sensor 100. As

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shown in Fig. 20, this conductive strip is, in the preferred embodiment, the narrower of the two strips 202 and 204 running along sensor connector tab 170 and leading to "capillary trap" measurement gap portion 160 of sensor 100 inside a diaper. Upon insertion of tab 170 of the sensor into receiving portion 600 of monitor unit 500, both these strips are connected to the monitor circuit 900 as shown by the dashed lines in Fig. 23, with wider conductive strip 202 bridging sensor-connector contacts SC2 and SC3 so as to connect the anode (in this embodiment) of the monitor's internal lithium "coin-cell" battery BTY to the 3-Volt "+V" supply bus of the circuit, and thus serving as the circuit's only power on/off switch. This advantageous arrangement, by which one "end" of the conductivity measuring circuit is common to the power supply bus of entire circuit 900, allows just one "extra" (third) contact SC3 (which can be either 620 or 622) in the monitor connector to provide (in conjunction with wider conductive strip 202) fully automatic master on/off control of the system. It is important that the voltage applied to SC1 and thereby to conductive strip 204 of the sensor is essentially equal to the constant +V (battery voltage) applied to SC2 and SC3 (and thus conductive strip 202) during all but the relatively brief (approximately 0.1-second) low-going pulses from U7 (occurring about every 3 seconds). As previously described, this low duty-cycle of applied voltage across the sensor minimizes ionic dissociation of the material to be sensed as well as the power consumption of the circuit due to current conduction through the sensor. As also previously described, the relatively fast transition-times of the pulses exploit the advantageous high-frequency skin-conductivity effect.

The low-going pulses from U7 are inverted by U8 and then applied to one input of AND gate U9. The other (preferably Schmitt trigger type) input of U9 is connected through a protective current-limiting resistor R3 (about 100 k-Ohms) to the sensor via sensor connector SC1, which is, in a preferred embodiment, the same as contact pin 624 of monitor 500. Resistor R3 and transient absorption devices Z1 and Z2 are used to protect the monitor circuitry from possible electrostatic-discharge (ESD) events during handling of the monitor unit or during operation in the use environment. Z1 and Z2 can be any suitable zener diode or other preferably fast response, high current semiconductor transient suppression device (such as General Instrument SA10A "Tranzorb" devices) with a rated breakdown voltage of about 10-Volts. These devices must also have maximum room-temperature reverse leakage below about 1 uAmp at +V (3-Volts). Capacitor C1 is preferably a 0.1-uF stacked-film type transient bypass device connected across the +V bus and circuit Common (-V). Because the CMOS devices in the monitor circuit are all lightly loaded, relative to the equivalent series resistance of lithium cell BTY, a single small power supply bypass capacitor is all that is necessary for the entire circuit. Neither the type, or value of C1 is particularly critical, but it should have good high frequency characteristics and low leakage (preferably well below 1 uAmp at +V).

The effective electrical impedance of disposable sensor 100 (RSNSR in parallel with CSNSR, connected between SC1 and SC2) acts, in conjunction with reference resistor R2, to divide the voltage pulses applied to one (preferably Schmitt-type) input of U9, such that the output of U9 will go high only during U7's relatively brief double output pulses, and only at such times that the sensor impedance falls from its initial value (typically at least several

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megOhms), to below about 500 kOhms due to the presence of either urine or feces bridging the conductive elements of the sensor within its capillary trap, as previously described. The simple "over-threshold" voltage determination of the "triggered" condition of the sensor by use of a Schmitt-trigger gate input of U9 is made feasible by the decisive, and relatively

5 long-lived conductivity-change produced by the structure of sensor 100 in response to either urine acting on the elimination-absorber, or due to the presence of fecal matter, as detected by monitor 500 with low duty-cycle, fast transition-time pulses. The lack of any requirement for relatively more power-consumptive and expensive precision comparator devices, as well as for any electronic latching function in the detection circuitry, are significant advantages of

10 the elimination-absorber monitoring system.

The hysteresis effect provided by the typical CMOS Schmitt-trigger input gate employed for U9 desirably prevents excessive current drain due to linear-region biasing of the gate, which would otherwise be produced by slowly-changing sensor conductivity. This hysteresis also prevents unstable or intermittent alarm activation when the sensor is

15 marginally "triggered". As will be apparent to those skilled in the art, the illustrated Schmitt-trigger input configuration of U9 (simplified for clarity) is not actually available as a single standard part, but the preferred Schmitt-trigger input capability can be readily provided by use of a separate Schmitt-type inverter (such as the 74HC14) in series with a standard AND gate (such as the 74HC08) or instead, the output of a standard Schmitt NAND (such as the

20 74HC 132) can be inverted to accomplish the same purpose. In fact, additional gate-delay in the sensor input (through R3) to U9 is desirable to ensure that narrow (and energy wasting) output "glitches" are not generated by U9 synchronous with the leading edge of each high-going input pulse arriving from U8, during the time periods when the sensor is being monitored, but is not yet triggered. This "gate-delay" method is more efficient than the

25 alternative of inserting an additional delay capacitor (connected to a supply rail) at the R3 input to U9.

In addition to acting as the detection threshold reference, resistor R2 also serves to limit the absolute maximum possible (short-circuit) current across SC1 and SC2/SC3 to about 1.5 uA during sensing pulses (and zero otherwise). R2, in conjunction with the rest of

30 the low duty-cycle sensing pulse circuitry, also severely minimizes discharge of the battery (which is sealed inside the monitor) in the unlikely event that all three of the unit's sensor-connector pins 620, 622 and 624, are somehow shorted together, even for lengthy periods. Because of the single-cell battery's relatively high equivalent series resistance and low (approximately 3 Volt) output, the monitor circuit pose no potential for harm to users even if

35 it were hypothetically applied directly across exposed wet skin bridging the connector contacts after a (worst-case) hypothetical short-circuit failure had somehow previously bridged Z2 and C1.

At any time that the attached sensor has become "triggered" as described above, the output of AND gate U9 continually produces short, double, positive-going pulses that are

40 approximately the logical complement of the original output of U7. These pulses are applied through a combination of steering-logic gates U3,U4,U10 and U11 to activate either an audible or a visible alarm, depending on the existing output state of "toggle flip-flop" U1. As

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shown in Fig. 23, when the sensor is "triggered" and output Q of U1 is high, the double pulses from U9 are allowed by OR gate U3 and AND gate U4 to enable U5 (a simple CMOS-gate R/C relaxation oscillator, shown as the box labeled "U5 BEEPER OSC" in Fig. 23), which generates a suitable "square-wave" output only during the duration of the double enabling pulses to drive a low-power electro-acoustic beeper BPR (i.e., transducer 810 of monitor unit 500) at near its resonant frequency (preferably approximately 2kHz) thereby producing a "double-beep", which preferably repeats approximately every 3 seconds. As will be apparent to those skilled in the electronic art, BEEPER OSC U5 can be implemented in a number of common ways, and it is also possible for U5 to be directly powered by the output of U4 instead of enabled by it. The use of a separate oscillator which remains either quiescent or is alternatively powered-off except during the brief alarm pulses is important to conserve battery energy. Transducer BPR (same as transducer 810 in a preferred embodiment) can be any suitable piezoelectric or electromechanical transducer, preferably with average drive current requirements in the 10 mA range at 1.5 to 3-Volts, and sound output level of about 80 dB(A) at 10 cm (such as the transducer previously described with respect to audible signal assembly 800). Similarly, when the sensor is "triggered" and output Q of U1 is alternatively low, the double pulses from U9 are allowed by OR gate U10 and AND gate U11 to turn-on (i.e., double flash) visible alarm device LED at current level of about 5-10 mA. The LED can be any high-brightness, low current type as previously described with respect to visual signal assembly 750.

As described above, the state of toggle flip-flop U1 controls which alarm mode (audible or visible) is activated after the attached sensor is triggered. U1 can be toggled by user operation of mode switch S1 (as previously described with respect to the mode change assembly 700), which acts to pull the "T" input of U1 logically high from the normally low state maintained by pull-down resistor R1 (approximately 100 kOhms) which is connected to circuit common (-V). This toggling of U1 can only occur, however, while the monitor circuit is switched on by the proper insertion of connector tab assembly 170 of sensor 100 into monitor 500. As previously described, the properly inserted sensor switches power to the monitor circuit by connecting contact 620 to contact 622 through the wider (202) of the sensor's two conductive strips 202 and 204. At any time that MODE SWITCH S1 is activated (while the monitor unit is properly connected to a sensor) and U1 is thereby toggled, either of ONE-SHOTs U2 or U6 is alternatively triggered. If output Q of U1 is asserted, this in turn activates ONE-SHOT U2 (which, like U6, can be any suitable standard low power monostable circuit). U2 then produces a brief (approximately 0.2 second) output pulse. This pulse then causes a similarly brief audible "BEEP" of transducer BPR by enabling BEEPER OSC U5 through gates U3 and U4. If alternatively, output Q-bar of U1 is asserted, visible alarm device LED is instead similarly activated via ONE-SHOT U6 and gates U10 and U11. Typical CMOS gates, as shown in Fig. 23, are capable of driving either of the alarm devices directly up to currents of a few milliamps. As will be appreciated by those skilled in the electronics art, either BPR or LED can optionally have suitable current-limiting resistors connected in series with these devices, to alter the trade-off between power consumption during alarm activation and either volume or brightness, respectively.

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As previously discussed, a truly convenient and reliable elimination-absorber monitoring system must have user interface and operating sequences that are exceptionally simple and intuitive. The present invention achieves this objective by means of its single mode switch and coupled alarm devices circuit combined with the automatic power switching of the system as described above, to provide all necessary operator interface functions for the monitoring system -- including both the convenient changeover from audible to visible alarm mode, as well as the inherent and unmistakable demonstration of which mode is currently selected. Activation of the mode switch also clearly verifies the proper connection of a disposable sensor to the monitor unit. As will be appreciated by those skilled in the electronics art, at the expense of likely greater complexity, cost and energy consumption, additional circuitry could easily be provided to expand the scope of the self-test function that is initiated by connection of a sensor and subsequent activation of the mode switch to test any other aspects of the monitor circuitry and/or the connected sensor, while still using the same alarm devices to indicate a "ready" or "OK" status. It is similarly possible to link the initiation of any other useful indications such as the time of day, etc., or even purely amusing sounds, etc. to activation of the mode switch by simply cascading these various events into a sequence and/or by employing additional indication devices. Those skilled in the electronics art will also recognize that numerous alternative arrangements or choices of oscillator types, logic chips and/or combinations of discrete components (including one or more custom or semi-custom integrated circuits) could possibly be used to implement various embodiments of the present invention without departing from this invention's basic elements and methods.

Microcontroller-Based Alternate Embodiments of Circuit 900

As examples of alternative embodiments of monitor circuit 900, **Fig. 24A, Fig. 24B, Fig. 24C and Fig. 24D** show four variations of alternative programmable microcontroller-based embodiments. As is well known by those involved with the electronics industry, several families of "low-end" CMOS microcontroller chips (such as a Microchip Technology PIC12CXX device shown in these diagrams), having various attractive specifications and capabilities, are available from a number of manufacturers at relatively low cost. The use of a microcontroller chip, instead of the discrete logic of **Fig. 23**, offers the advantage of lower component-count on the monitor unit's circuit board and as a result, also likely lower assembly cost. A microcontroller-based embodiment may also minimize the range of observed variations in the time-based functions of the monitor system from unit to unit, by reducing the number of separate resistor/capacitor time-constant combinations needed, although this is not really a critical issue, given the low timing precision required (probably no better than about +/- 10% , in general). Another possible advantage would be the relative ease of changing timing values or other aspects of the monitor system's operation, if desired, by revising the firmware programmed into the microcontroller chip -- instead of by changing component values or other hardware. Also, the different functions can easily have separate timing constants without incurring the overhead of additional hardware (such as durations used for sensor-pulsing vs. alarm indication, or audible vs. visual alarm indication).

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Fig. 24A shows an alternate embodiment of the present invention wherein a PIC 12Cxx microcontroller U1-24A executes programmable code (i.e., firmware) as represented by the flow-chart shown in Fig. 25. Only a single oscillator is needed, because the PIC microcontroller has an internal clock oscillator whose frequency is determined by external R/C components R4-24A and C2-24A which can clock the microcontroller continuously while a sensor is connected to switch-on power. With suitable timing provided by either firmware or on-chip timer delays, the microcontroller chip runs a continuous "monitor loop" as shown in the flow chart during which it repeatedly polls (and debounces) mode switch S1 (approximately every 0.1-second), pulses and monitors the connected sensor 100 (about every 3 seconds), and also generates, when appropriate, suitable alarm signals to drive BPR and LED -- in effect approximately emulating the functions of the discrete embodiment of Fig. 23. Note that the user interface, the control sequences and sensing methods, the automatic power switching of battery BTY via sensor connections SC2 and SC3 (contact pins 620/624), and the ESD protection and bypass configurations are all essentially the same as in the discrete logic embodiment of Fig. 23. Also note that microcontroller U1-24A even has a Schmitt-trigger input line I2 connected to the same resistor network for the sensing portion of the circuit, as described in the discrete logic embodiment. A significant difference in this embodiment (as compared to the previous discrete logic version of Fig. 23) is that here the sensor can, without extra hardware, be advantageously pulsed with much narrower, single pulses (approximately 10- milliseconds long) as opposed to the double 0.1-second pulses or single 0.2-second pulses that are used for alarm or mode-change indications, respectively. As will be appreciated by those skilled in the electronics and firmware programming arts, numerous alternative arrangements or choices of oscillator type, microcontroller chip and configuration of I/O (i.e., input/output) lines as well as various firmware implementations could possibly be used to produce various embodiments of the present invention without departing from this invention's basic elements and unique combination of methods.

On the other hand, likely disadvantages of a microcontroller-based embodiment of monitor circuit 900, relative to the discrete-logic version of Fig. 23, include dependence on a sole-sourced key component (the microcontroller chip itself), possible increased susceptibility to improper operation due to electrical noise or interference, and relatively greater energy consumption. As will be appreciated by those skilled in the art, noise and interference susceptibility can be a problem with microcontroller-based systems in general, usually due to unintended resetting of data stored in RAM (random access memory) registers. Such an event is particularly troublesome if the data corrupted is critical to functions of the system, and most especially so if program flow is altered due to corruption of the microcontroller's program-instruction counter (which causes unexpected and possibly unacceptable "jumps" in program execution). So-called "watchdog timers" are commonly used to automatically reset the program counter in case of such gross occurrences where the program execution has "hung up" for more than a certain period of time (the PIC microcontroller chips shown in Fig. 24A, Fig. 24B, Fig. 24C, and Fig. 24D, each have a built-in watchdog timer that could optionally be used for this purpose), but this alternative

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comes with the expense of added power consumption to continuously run the watchdog oscillator and counter.

Relatively increased power consumption by a microcontroller-based embodiment or the present invention stems mainly from the otherwise core advantage of programmed logic in general, i.e., the substitution of program-code execution by the microcontroller for
 5 dedicated hardware. Microcontrollers typically require several clock cycles to accomplish the execution of a single program instruction, and they must therefore have a clock frequency several times higher than the highest repetition rate of any output signal to be generated by execution of firmware. This means that if, in the pursuit of minimum
 10 component-count, a microcontroller is employed to generate a 2-kHz square wave signal to drive the audible alarm device of the present invention (as shown in **Fig. 24A**) the input clock frequency for the microcontroller (in this case) would have to be at least 16 kHz. Because total power consumption in CMOS logic is nearly proportional to clock frequency, this arrangement is considerably more energy-expensive than using a 2-kHz oscillator.
 15 Also, generation of a continuous 2-kHz square wave for approximately 0.1-second long takes many (hundreds in this case) bytes of instruction code if the microcontroller cycle-time is so slow as to need fully linear coding (where an output line is turned ON/OFF/ON/OFF...etc., with successive instructions continuously executed for 0.1-second).

For the above reason, the circuit of **Fig. 24A** can be modified into the version shown
 20 in **Fig. 24B**, wherein the pulses from a 2-KH oscillator OSC are used to clock a PIC 12Cxx microcontroller U1-24B, and are also gated (using an additional logic chip U2-24B under firmware control via an output line O1 of microcontroller U1-24B) directly to audible alarm transducer BPR. With this circuit, the microcontroller can now be clocked at the same 2-kHz frequency used for alarm signals. Although this arrangement is more energy conservative
 25 than that of **Fig. 24A**, it still requires the microcontroller to be clocked at 2-kHz – a considerably faster rate than is needed to accomplish any of the monitor unit's other functions via the execution of firmware.

Fig. 24C shows another variation of a microcontroller-based monitor embodiment where a separate hardware 2-KHz oscillator OSC (similar to U5 BEEPER OSC as used in
 30 the discrete embodiment of **Fig. 23**) is employed and where a PIC 12Cxx microcontroller U1-24C is clocked at the minimum rate (approximately 128 Hz) needed for it to accomplish all needed functions (without use of interrupt-driven code) other than direct audible tone generation. As will be apparent to those skilled in the art, it is alternatively possible in designs with various available microcontroller chips for a relatively slow clock oscillator
 35 (operating at 128 Hz, for example) to be combined with a frequency divider to periodically "wake-up" the microcontroller from a relatively lower-current "sleep" mode by resetting it each time it wakes up (every 3-seconds, for example), thereby combining, in the context of the present invention, the features of even lower average frequency clocking with repetitive resets which can effect recovery from "hang-up" events without the current consumption drawback of a dedicated watchdog timer. With this approach, the input employed to monitor
 40 mode switch S1 would have to be configured to wake up the microcontroller from "sleep" directly upon operation of the switch instead of the switch input being polled by the

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microcontroller only every 3-seconds (during each wake-up period), in order to provide adequately fast switch response time, even if the switch is momentarily operated while the microcontroller happens to be "asleep".

Finally, **Fig. 24D** shows a compromise variation of monitor circuit 900 where a PIC 12Cxx microcontroller U1-24D has its clock oscillator frequency dynamically changeable under firmware control, from a 128-Hz rate needed for most of the monitor's functions to a 16-kHz rate necessary for direct audible alarm drive at 2-kHz. This is done by using the corresponding output line O4-24D, of microcontroller U1-24D, that pulses the sensor -- to also simultaneously increase the charging current available to the microcontroller's internal relaxation oscillator through additional resistor R5-24D (and thereby to increase the frequency of oscillation for short bursts, when needed). Also added, in this embodiment, is the blocking-diode D1-24D (any low-leakage type such as a 1N4151), which eliminates reverse current flow when the output line is returned to the low condition, causing the clock frequency to return to the 128-Hz rate. Although any alternative microcontroller chip and/or available output line could be used for the purpose of clock frequency changing, because the inexpensive PIC chip shown is packaged as an 8-pin device, there is no separate I/O line available. This means that the microcontroller must run at 16-kHz throughout the duration of each sensing pulse, but the sensing pulses can be easily made much shorter than the 0.1-sec used in the discrete embodiment of **Fig. 23**, because the microcontroller does not need additional hardware to provide suitably longer pulses (after the sensor has been triggered) for alarm indications. Pulses can be produced by the microcontroller with minimum duration equal to four clock periods (a single instruction time) without additional hardware. Thus, the "pre-triggered" sensing pulses (and hence the pre-triggered periods of relatively higher current operation can be less than one millisecond long, to both conserve energy and reduce the ionic-dissociation effect (previously described). Also, as shown in **Fig. 24D**, in order to allow the sensor-pulsing output line of microcontroller U1-24D to have the correct logic sense (i.e., go "high" when asserted), for appropriately accelerating the clock oscillator, the power-switching sensor contacts SC2 and SC3 are connected so as to switch the common end (i.e., -V) of battery BTY-24D instead of the +V end as in the previously described circuit 900 embodiments (**Fig. 23** and **Fig. 24A**, **Fig. 24B**, and **Fig. 24C**). This arrangement ensures that zero voltage is applied across the sensor, except during the low duty-cycle sensing pulses, and also that the fast transition-time of the pulses can exploit the high-frequency signal propagation characteristics of the material to be sensed, just as in the previous embodiments as described.

System Energy Requirements And Battery Life

A key requirement for a practical elimination-absorber monitoring system is that it be capable of continuous use for the entire diaper-wearing portion (typically the first 2 years) of a baby's life, without need for either battery changing or recharging. Based on many laboratory measurements, the electronic circuit using the methods and control strategies of the present invention, as shown in **Fig. 23**, typically operates at such low total energy consumption, that two full years of continuous operation (after extended storage) can be

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confidently expected with the system's single 560 mA-Hour, 3 Volt lithium coin cell BTY unit (such as a Panasonic CR2354). Cell BTY is intended to be permanently sealed into monitor unit 500 during the manufacturing process. The maximum electrical current requirements and resulting battery life are calculated as follows by using the relationship:

5

$$\text{Average Current} = (\text{Instantaneous Current}) \times (\text{Duty-Cycle}).$$

Adding the components of average current for the three operating states of the monitor system:

10 Pre-Trigger Current + Mode-Changing and Self-test Current + Post-Trigger Current = Total Average Current , where:

$$\text{Pre-Trigger Current (includes periodic sensor-pulsing)} = 4.0 \text{ uA};$$

15 Mode-Changing and Self-Test Current (includes alarm device drive current and assumes that there are an average of 20 Mode-Changes per day over the useful life of the monitor unit, and that each Mode-Change is indicated by a 0.2-second alarm-device beep or flash),

$$\text{Alarm-On Current} \times \text{Mode-Changes} \times \text{Alarm Pulse Time} \\ 8.0\text{mA} \times (20 \text{ events} / 24\text{-Hrs}) \times (0.20\text{-sec}) \times (1\text{-Hr} / 3,600\text{-sec}) = 0.4 \text{ uA and}$$

20

Post-trigger Current (includes alarm device drive current and assumes that there are an average of 5 diaper-changes per day over the useful life of the monitor unit, and that each alarm continues for an average of 12-minutes before each soiled diaper/sensor is changed and the alarm stops, and that the alarm indications consist 1of two 0.1-second beeps or

25

$$\text{Alarm-On Current} \times \text{Alarm Events} \times \text{Alarm Pulse Time} \\ 8.0\text{mA} \times (5 \text{ alarms} \times 0.20\text{-Hr} / 24\text{-Hrs}) \times (0.20\text{-sec} / 3.0\text{-sec}) = 22.2 \text{ uA}$$

$$\text{To yield a } \text{Total Average Current} = 26.6 \text{ uA}$$

30

Assuming that, for the lithium cell employed, voltage remains essentially constant for the useful life of the cell (the most stringent assumption for calculating Battery Life),

$$\text{Battery Life} = \text{Cell Capacity} / \text{Total Average Current} = (560 \text{ mA-hrs} / 26.6 \text{ uA}) \\ \times (1\text{-Year} / 8,760 \text{ Hours}) = 2.40 \text{ Years}$$

35

The above calculated Battery Life is preferably adjusted downward by a 15% factor to compensate for possible high-temperature storage prior to normal use and for variations in individual battery performance, and also to include a miscellaneous safety factor. With this adjustment, monitor unit 500 of the present invention has a calculated net continuous

40

operating life:

$$0.85 \times 2.40 \text{ Years} = \underline{2.04 \text{ Years}}$$

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Note: In actuality, all the current consumption values shown above are functions of operating voltage (+V), which can be expected to decrease non-linearly to about +2.5-Volts through the operating life of the battery. This fact effectively adds an additional safety factor for the calculated battery life, because in use the actual average current values will all be somewhat lower than those specified above. Actual battery performance depends both on the peak as well as the average discharge current levels, and both these values are well within the range specified by the battery manufacturer with respect to the Cell Capacity (560 mA-hrs) used in the calculation above. Some of the timing assumptions for typically caregiver-determined changes of operating state in the above calculation (such as 12 minutes of uninterrupted alarm indication before each change) are likely rather conservative and could reasonably be modified to extend the calculated battery life specification to 2-1/2 or even 3 years if such specification is deemed more appropriate based on further market research. Alternatively, the actual monitor unit internal electronic timing can be easily modified (such as by increasing the 3-second spacing, or by reducing the 0.1-second width of the alarm pulses) to achieve the same objective.

System Test Device

A diaper-simulating, test strip device 950, for use with the elimination-absorber monitoring system, is shown in Fig. 30A and Fig. 30B. The test strip has a substrate consisting of a thin tab 960, of electrically insulating material. Tab 960 has length and width similar to that of connector tab stiffener 166 of sensor 100 (as previously described), and can be made from the same material (such as 0.010-thick polyester sheet). This tab has a side 961 (illustrated in Fig. 30A), with a first area 964 of relatively electrically-conductive coating (such as thin, i.e., 0.001-inch, aluminum foil or other suitable material) disposed as shown. Side 961 also has a second area 965 of relatively electrically-conductive coating, which is separated from area 964 by an insulating gap 966. A chip resistor (or other device) 968 is preferably disposed on side 961, to bridge areas 964 and 965. Device 968 effectively simulates the value of conductivity that would be measured by monitor 500 (across channel 166, and thus between conductive strips 202 and 204 of a connected sensor 100), when a very small quantity of fecal matter is present in a sensor-equipped diaper. This device and its value (preferably a chip resistor, with value approximately 1.5-2.0 MegOhms, or other appropriate device such as a chip capacitor) are selected to have conductivity (as measured by the monitor) somewhat greater than, but approximately corresponding to, the minimum presentation of fecal matter required for monitor 500 to initiate alarm indications (as has been previously described). The tab's opposite side 962 (illustrated in Fig. 30B) has area 967 of relatively electrically-conductive coating, which is preferably equivalent in all aspects to first area coating 964 on side 961. Side 962 does not, however, have a conductive area corresponding to second area 965.

When substituted for sensor 100 (by simply being inserted into slot 600/610 of monitor 500), the test strip bridges contacts 620 and 622 in unit 500, thereby connecting power in the monitor circuit. Depending on which way the strip is inserted (i.e., which side is "up"), the strip also simulates either a "triggered" or "un-triggered" sensor. With this

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arrangement, only insertion of the test strip with side 961 "facing up" effectively connects device 968 between monitor contact 624 and contacts 620/622, thereby simulating the "triggered" state. The test strip is preferably provided with a pair distinctive indicative markings 971 and 972 on sides 961 and 962 respectively, so that the user can easily select the desired function. In a preferred embodiment, there also may be provided a suitable hole or opening 974 for the purpose of conveniently retaining the test strip device on a key-ring, thus providing quick access to, and avoiding loss of the relatively small test strip.

In an alternate embodiment, test strip 950 could have a single larger conductive area on side 961, combining areas 964 and 965 and thus eliminating gap 966, or areas 964 and 965 could be connected by a conductive trace or other shunt. Such arrangement would function similarly to the embodiment previously described, but would not verify the sensitivity of the system – rather only its more basic operational status. Alternatively, a test strip device could have suitable disposition of one or more conductive surfaces or reference devices corresponding to the function of side 961 substantially on one end, and at the other end (on the same side) have elements functionally corresponding to side 962, so that rotation of the strip end-for-end, instead of turning it over, would accomplish the same purpose. As will be readily apparent to those skilled in the relevant arts, various geometric shapes and orientations of relatively electrically-conductive and also relatively non-conductive surfaces could be alternatively disposed on, or within any suitable piece or assembly of material so as to appropriately simulate the connection of either a triggered or an un-triggered sensor, and thereby appropriately activate the monitor unit of an elimination-absorber monitoring system. Either the positional orientation of the test device and/or the monitor unit can be changed to allow a single device to simulate either sensor state, or alternatively two separate devices can be employed.

This simple and inexpensive device is useful in several use-environment situations, such as for demonstrating the alarm modes and "triggered" operation of the monitor to a new caregiver, or for verifying that foreign material (such as adhesive or dust) has not accumulated in the connector area of the monitor unit (to cause false triggering or prevent proper sensor connection), or that the connector spring or other means has not been bent or compromised so as to prevent proper connection to the sensor (and therefore requiring cleaning or replacement of a clip or other portion of the connector means).

MANUFACTURE AND ASSEMBLY

Manufacture and Assembly of Sensor 100

The materials employed in manufacture of sensor 100 are, to the extent possible, biodegradable, non-toxic, light, and readily available in large quantities. The various sensor embodiments can be manufactured by simple manual processes. For example, pre-punched layers can be aligned and affixed via the respective adhesive substrates, followed by wrapping with the protective peel-off cover. Alternatively and much preferably, high-speed, continuous strip production methods can be used. For example, the various layers can be assembled by: heat cured, co-reactive or catalyst cured adhesives, contact or

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pressure-sensitive adhesives, heat staking, hot-rolling or pressing, ultrasonic welding, induction heating (in the case of metallic strips), stapling, eyeletting, riveting and the like.

In one representative sequence, the component materials are provided already cut to width, perforated (in any or all cases) and spooled on large rolls, to be fed into the manufacturing process. The various layers can be pre-punched on the reel before assembly, or on the way to the joining point. Some or all of the components could be laminated between pressure rollers or plates into a continuous multi-layer strip, or alternatively, certain components or sub-assemblies could be fed as pre-cut components and "dropped" onto a moving substrate strip at the appropriate locations, prior to a final "cut-off" step for each finished unit.

Additional alternative embodiments of layer construction, other than those previously and specifically described, may be preferred to maximize the number of tape-like materials employed in the manufacturing process, to be continuously laminated from bulk supply reels prior to final cutoff of finished sensors, thereby minimizing lateral combination of pre-cut piecewise materials but potentially inserting the requirement for selective adhesive application and/or bonding processes instead of, or in addition to, the use of prefabricated "double-sticky" tapes. In one preferred manufacturing process, the second double-sided adhesive layer 300 is the first component fed into the process. As mentioned previously, layer 300 can be supplied with adhesive already attached, or the adhesive(s) can be applied to suitable portions of both its surfaces as the first step, i.e., prior to attaching layers 250 and 350, but preferably after the perforations in layer 300 are punched or cut out, to avoid or minimize the production of sticky punched fragments. Holes 310 along the edges of layer 300 may advantageously (in addition to their other functions) serve as "sprocket holes" to facilitate the precise, high-speed transport of roll or sheet-fed sensors through the assembly process. Alternatively, the sensors could be laminated with several, or many units in parallel out of wider material rolls, with the final cut-off being more like a "cookie-cutter" operation than like a "taffy-cutter" one. In still another variation, some or all of the components could be "stack laminated" in a fixture, either "one-up" or "many-up" in large sheets.

Embodiments of sensor 100 that are intended for direct-incorporation into diapers can utilize any of the previously described variations of portion 450, either disposed on, or integrated with portion 474 on the front of the diapers. The in-diaper portion can be simply laminated into the diaper, either sequentially or simultaneously during the manufacturing process, with conventional diaper layers being suitably modified as is necessary.

The manufacturing process adjustments necessary to produce the various embodiments of sensor 100 will be apparent to those of ordinary skill in the art. Manufacture of the sensor embodiment that is incorporated as part of a disposable diaper, as opposed to an add-on to a diaper, will take account of the materials used and assembly process for that particular diaper. Alternatively, a separate and relatively complete sensor can simply be applied to the inner lining of a disposable diaper as a final step in an otherwise conventional diaper manufacturing process.

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Manufacture and Assembly of Monitor 500

The monitor is manufactured using techniques that are standard in the electronics industry, for the processing of through-hole and/or surface-mount technology components on typical printed circuit board materials. In one example manufacturing sequence for a preferred embodiment as shown in **Fig. 29A** (and referring to **Fig. 21A**), all circuit components including lithium coin-cell BTY, including three sensor connector contact pin sockets 621, 623 and 625 (but excepting contact pins 620, 622 and 624), are mounted and/or soldered on a single, small (approximately 1.2 inch x 2.0 inch x 0.06 inch thick) rigid printed circuit board 905 which, after assembly, soldering, cleaning and test, is "plugged" onto connector contact pins 620, 622 and 624 which have been previously inserted through molded plastic back case portion 514. These pins may be inserted and sealed in place by several methods, including press-fitting, hot-pressing, induction heating, ultrasonic welding, or insert-molding into the back case portion – or encapsulated via "potting" of the monitor case with a suitable waterproof filler such as epoxy resin or silicone rubber, thus simplifying reliable liquid-tight sealing of the assembly during its manufacture and also increasing its ruggedness. The heads of the contact pins are exposed in connector recess area 600, so that their shank portions protrude through, and continue into the interior of the case, passing through the plane of printed circuit board 905. The circuit board incorporates suitable miniature through-hole sockets 621, 623, and 625. These sockets are preferably of the gold-plated, wiping contact-spring type, to receive and reliably interconnect the contact pins. The fact that entire, fully-functional electronic circuit board assembly 910 comprises a single sub-unit that is independent of its case (and that can be easily tested and placed in inventory for later packaging) is a substantial advantage of this embodiment.

At this point, circuit assembly 910 is preferably held in place by suitable protruding and supporting features in the mating portions 512 and 514 of the case 510, then one or more of several standard coating/potting/sealing methods is used (such as epoxy resin or silicone injection) to both seal and mechanically protect the unit. The front case portion can be physically bonded to the back portion by the same process that seals and protects the case, or it can be separately attached by another process step such as ultrasonic welding. Alternatively, the internal "potting" or injection of other filling material (including inert gas or partial evacuation of the case) can be done either after, or simultaneously as, the two case portions are joined. Next, faceplate overlay 517 is adhered to the shallow aligning recess in the front face surface of upper case portion 512. Spring clip/plate 610 can be attached to recess 600 in back case portion 514 as a final step, or at any earlier time after the contact connector pins are inserted into the back case portion.

Fig. 29B illustrates an assembly sequence for an alternate version of monitor unit 500, that employs an edge-type embodiment of the flex-tab connector means as shown in **Fig. 21B**. In this situation, three flat edge-type contact springs 621-A, 623-A and 625-A are disposed on circuit board 905, and are designed to press securely against the shanks of contact pins 620, 622, and 624, when circuit assembly 910 is pressed into place inside back case portion 514. An alternative embodiment (to 610) of connector clip/plate 610-A is retained by a pair of dovetail slots 617 in case section 514. Other more detailed process

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variations potentially suitable for assembly of monitor/alarm 500 will no doubt be apparent to those skilled in the electronics manufacturing art, in light of these specifications.

METHODS OF USE

5 **Application to a Disposable Diaper** (Refer to Fig. 2A)

10 Sensor 100 is unwrapped from protective bottom cover 110, revealing lower adhesive 156 of layer 150 and exposed adhesive 456 on the bottom edges of layer 300, as well as adhesive 456 on the bottom of layer 452. Cover 110 is disposed of. Sensor 100 is positioned above a diaper, centering fold line 342 over the top front rim, with portion 450 extending over the outside front of the diaper. While stretching the diaper flat, the "inside-diaper" portion of sensor 100 is smoothed into place. The upper portion of sensor 100 that protrudes proximally over fold line 342 is adhered to (typically plastic-coated) section 474 of the diaper by adhesive 456. (This diaper can now be set aside for later use.)

15 **Attachment of the Monitor/Alarm** (Refer to Fig. 2B)

20 Top protective layer 455 is peeled off and discarded. Holding monitor unit 500 in one hand, connector tab 170 is inserted fully into slot 600/610 at the top edge of the monitor as the monitor is engaged with locating block 470. While holding monitor 500 in place, the end of translucent flap 460 is grasped and stretched firmly over the top of the unit. The proximal portion of the flap is then contacted with the exposed adhesive 304 exposed at the top front of the diaper, securing the monitor from tampering or removal.

Operation (Refer to Fig. 2B)

25 Using a finger tip, dot 702 on the face of monitor 500 (covering mode-change assembly 700) is momentarily pressed to select either the "beep" or the "blink" mode. If a "beep" is heard – the unit is set to beep; if indicating light 750 blinks in upper "balloon" symbol 518 on the monitor face – it is set to blink. Such response also verifies proper monitor operation and that sensor 100 is properly mated (and thus connected with) the monitor unit. The dot can be pressed again at any time to change the beep/blink mode.

30 Subsequent automatic recurring activation of either audible or visual indicators means that a "diaper needs changing" condition exists.

Removal (Refer to Fig. 2B)

35 When changing diapers, to remove the monitor unit -- edge of pull-tab 463 of translucent flap 460 of the sensor is grasped and pulled down away from the diaper. The monitor unit is lifted slightly (away from engagement with locating block 470) and it is slid straight downward -- away from tab 170. The diaper and attached sensor pad are discarded as usual, and diaper monitor 500 is ready to be attached to a sensor on the next diaper.

40 **EXAMPLE** (The following example should not be considered as limiting the scope of the invention, but merely as being illustrative and representative thereof.)

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Preliminary In-Use Effectiveness Tests and Summary of Results

The elimination-absorber monitoring system (shown in Fig. 2B) was initially use-tested in multiple two, three and four-day sessions with a healthy male child subject, beginning at age 8 months. The caregivers in these trials were the adult parents of the test subject. After receiving basic instruction in use of the system, the caregivers unwrapped and applied prototype disposable sensors to various popular brands and models typical of commercially available disposable diapers ("one-at-a-time", just before each diaper change) according to the "method of use" procedure as previously described. In each test session, approximately 20 disposable sensors were used, with each sensor being applied by one of the caregivers. Each sensor's performance (relative to the caregivers' expectations) was discussed and noted by an observer after the next change of diaper. Caregiver comments were also noted immediately after each application of the sensor and monitor to the diapers. The results of inspecting the soiled diapers (as well as any general observations by the caregivers during use of the system) were discussed and recorded after each change cycle. None of the test subject's or caregivers' routine activities were restricted or modified, other than by the application of sensor and removal/re-application of the monitor unit during diaper changes, and also by occasional activation of the monitor's "mode-switch" by the caregivers. Mode-switch activation was done to verify system operation after each diaper change, and to select either the audible or the visible alarm mode, as the caregivers desired. For example, the visible alarm mode was always selected for privacy (and confidentiality) when outside a controlled-access test facility.

In each instance, according to the caregivers, the system appeared to respond to the appropriate alarm criteria. There were no observed false positive or false negative responses. In reporting their conclusions after completion of the tests, the caregivers expressed the opinions that their use of the system had resulted in significantly improved convenience of care. In several instances, they also reported that use of the system had initiated more timely diaper changes than would likely have occurred with use of their conventional checking methods. Moreover, the resulting monitor-suggested diaper change intervals appeared to closely replicate the expected "norm" as had been previously observed when only traditional methods were used. In summary, the elimination-absorber monitoring system functioned as intended, in accordance with the criteria of the present specification.

VARIATIONS OF THE DISCLOSED EMBODIMENTS

While the present invention has been described with reference to the specific embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt a particular situation, material, composition of matter, process, process step or steps, to the objective, spirit and scope of the present invention. Any such modifications are intended to be within the scope of the claims appended hereto. All patents and publications cited above are hereby incorporated by reference.

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WHAT IS CLAIMED IS:

1. A sensor for use with an elimination-absorber monitoring system, said sensor comprising sensing means and a flow-baffling layer disposed to divert direct flow of a liquid to be sensed around said flow-baffling layer prior to detection by said sensing means.

2. The sensor of claim 1 comprising a first liquid-permeable flow-conducting layer disposed adjacent said flow-baffling layer on the side of said flow-baffling layer opposite said sensing means, to collect and conduct a liquid to be sensed across said flow-baffling layer.

3. The sensor of claim 2 comprising a second liquid-permeable flow-conducting layer, disposed opposite said first flow-conducting layer relative to said flow-baffling layer, to conduct liquid from said first flow-conducting layer, around said flow-baffling layer and toward said sensing means.

4. The sensor of claim 3 wherein adjacent portions of said first and second liquid-permeable flow-conducting layers extend beyond an outer edge of said flow-baffling layer and are in fluid communication to conduct liquid around said flow-baffling layer and into said second flow-conducting layer.

5. The sensor of claim 4 wherein a portion of said first liquid-permeable flow-conducting layer extends beyond an outer edge of said second liquid-permeable flow conducting layer to conduct liquid to an elimination-absorber.

6. The sensor of claim 1 comprising a cover layer disposed on the side of said flow-baffling layer farthest from said sensing means, and a liquid-permeable flow-conducting layer disposed on the side of said flow-baffling layer closest to said sensing means to conduct liquid around said flow baffling layer and toward said sensing means.

7. The sensor of claim 6 further comprising a relatively liquid-impermeable layer disposed opposite said sensing means with respect to said flow-baffling layer.

8. The sensor of claim 3 comprising a first series of openings through and disposed toward the outer edges of said flow-baffling layer to conduct liquid from said first flow-conducting layer, through said flow-baffling layer and to said second flow-conducting layer.

9. The sensor of claim 8 comprising a second series of openings through said flow-baffling layer, disposed between said first series of openings and the outer edges of said flow-baffling layer to conduct liquid from said first flow-conducting layer, through said flow-baffling layer, to an elimination-absorber.

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10. The sensor of claim 3 comprising a relatively liquid-impermeable layer disposed opposite said flow-baffling layer with respect to said sensing means and said second flow-conducting layer to form a capillary channel within said sensing means.

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11. The sensor of claim 10 wherein:

adjacent portions of said first and second liquid-permeable flow-conducting layers extend beyond an outer edge of said flow-baffling layer and are in fluid communication to conduct liquid around said flow-baffling layer and into said second flow-conducting layer, and

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a portion of said first liquid-permeable flow-conducting layer extends beyond an outer edge of said second liquid-permeable flow conducting layer.

12. The sensor of claim 1 comprising a series of openings through said flow-baffling layer of sufficient size and shape to permit the passage of fecal matter to contact said sensing means, while deterring contact between said sensing means and the skin of a wearer of the elimination-absorber.

15

13. The sensor of claim 12 wherein said openings are disposed posterior to the sensor portion most likely to be directly impacted by a drop or stream of urine.

20

14. The sensor of claim 4 comprising a third series of openings through said flow-baffling layer of sufficient size and shape to permit the passage of fecal matter to contact said sensing means while, when taken together with the thickness of said layers, deterring contact between said sensing means and the skin of a wearer of the elimination-absorber, said third series of openings being disposed posterior to the sensor portion most likely to be directly impacted by a drop or stream of urine, there being no liquid conduction between said first flow-conducting layer and said second flow-conducting layer or said sensing means through said third series of openings.

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15. The sensor of claim 14 wherein said sensor is incorporated as part of a disposable diaper.

16. The sensor of claim 14 wherein said sensor is adapted for application to an elimination-absorber, comprising:

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means for affixing said sensor to the elimination-absorber, and

an optional cover layer for separating said first flow-conducting layer from the skin of a wearer of the elimination-absorber.

40

17. The sensor of claim 3 wherein said second flow-conducting layer is selected from a material that is less absorbent than a dry elimination-absorber, but more absorbent than an elimination-absorber sufficiently wetted to need to be changed.

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18. The sensor of claim 3 wherein said second flow-conducting layer is configured in size and materials to delay the conduct of the liquid from the first conducting-layer to the sensing means until the elimination-absorber is sufficiently wetted to need to be changed.

5

19. A sensor for use with an elimination-absorber monitoring system, said sensor comprising a layer, sensing means disposed beneath said layer and a series of openings through said layer, said openings being of sufficient size, shape and thickness to permit the passage of fecal matter to contact said sensing means, while deterring contact between said

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20. The sensor of claim 19 wherein each of said openings is disposed posterior to the sensor portion most likely to be directly impacted by a drop or stream of urine.

15

21. The sensor of claim 20 wherein said layer is sufficiently absorbent to retain and thereby prevent small volumes of liquid or condensation from penetrating said openings and being detected by said sensing means.

20

22. The sensor of claim 21 further comprising a relatively liquid-impermeable layer disposed above, below or within said absorbent layer, said openings being continuous through said absorbent and liquid-impermeable layers.

25

23. The sensor of claim 22 wherein said liquid-impermeable layer is relatively hydrophobic as compared to said absorbent layer even when said absorbent material becomes saturated.

24. The sensor of claim 22 wherein said absorbent layer is bounded by said liquid-impermeable layer to direct the flow of liquid away from said openings.

30

25. The sensor of claim 19 further comprising a cover layer disposed adjacent said layer opposite said sensing means, said cover layer having nominally closed slits/flaps covering said openings, said slits/flaps being resistant to passage of urine but displaceable by contact with feces to permit the passage of fecal matter into the openings.

35

26. A monitor/alarm unit retainer for use with an elimination-absorber monitoring system having an elimination-absorber/sensor unit and a monitor/alarm unit, said retainer comprising:

an elastic or semi-elastic flap adapted to be stretched over said monitor/alarm unit, said flap having a monitor/alarm unit contacting portion that is substantially free of adhesive, said monitor/alarm unit contacting portion being at least partially surrounded by a second portion having sufficient adhesive for retention on an elimination-absorber or the elimination-absorber/sensor unit, thereby facilitating ready and clean release of the monitor/alarm unit

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from the retainer when desired; and

a locating block and a reciprocally shaped receiving portion disposed respectively on said elimination-absorber/sensor unit or said monitor/alarm unit to prevent movement of said monitor/alarm unit and maintain alignment between protruding tab and barbless receiving slot connection means of said units while said flap is stretched over said elimination-absorber monitor/alarm unit.

27. The sensor of claim 15 further comprising a monitor/alarm unit retainer, said retainer comprising:

an interlocking protruding or receiving portion corresponding with a mating portion on an elimination-absorber monitor, and

an elastic or semi-elastic flap adapted to be stretched over a monitor/alarm unit, said flap being permanently attached at a distal end to said sensor or said elimination-absorber, and having a proximal end a portion of which is adapted to be releaseably adhered to said sensor, said elimination-absorber, or to another portion of said flap.

28. The sensor of claim 16 further comprising a monitor/alarm unit retainer, said retainer comprising:

an interlocking protruding or receiving portion, corresponding with a mating portion on an elimination-absorber monitor, having adhesive means for attachment to the elimination-absorber, and

an elastic or semi-elastic flap adapted to be stretched over a monitor/alarm unit, said flap pending from the distal end of said protruding or receiving portion and having a proximal end, a portion of which is adapted to be releaseably adhered to said sensor or said elimination-absorber.

29. A releasable circuit electrical connector, said connector comprising a flexible tab portion and a tab-receiving portion,

said tab portion having two or more conductive members disposed on a resilient support, and

said tab-receiving portion having two or more protruding contacts arranged to complete a circuit with said conductive members, lateral surfaces for guiding and positioning said tab, and having means to deform said resilient support into a substantially wave-like cross-section thereby retaining said tab portion while maintaining said tab portion's orientation and pressure against said contacts to ensure continuous electrical connection of said conductive members with said contacts.

30. The sensor of claim 27 further comprising a releasable circuit electrical connector, said connector comprising a flexible tab portion adapted to be received in a tab-receiving portion of an elimination-absorber monitor,

said tab portion having two or more conductive members of said sensing means disposed on a resilient support.

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31. The sensor of claim 30 wherein said tab portion is disposed through a front surface of said diaper above said interlocking protruding or receiving portion.

5 32. The sensor of claim 28 further comprising a releasable circuit electrical connector, said connector comprising a flexible tab portion adapted to be received in a tab-receiving portion of an elimination-absorber monitor,
said tab portion having two or more conductive members of said sensing means disposed on a resilient support.

10 33. An elimination-absorber monitoring system kit having a sensor of claim 30 and a monitor/alarm unit that comprises: a power source,
an alarm means,

15 an interlocking protruding or receiving portion corresponding with the portion on said monitor/alarm unit retainer,

a releasable sensor connector comprising a tab-receiving portion having two or more protruding contacts arranged to engage said conductive members, lateral surfaces for guiding and positioning said tab, and having means to deform said resilient support thereby retaining said tab portion while maintaining its orientation and pressure against said contacts to ensure continuous electrical connection of said conductive members with said contacts, and

20 electronic circuitry employing relatively narrow, relatively low duty-cycle pulses to measure conductivity or capacitance between a pair of spaced conductors or semiconductors that are disposed within or that span an appropriate measurement path relative to the elimination-absorber to be monitored and actuates said alarm means when the elimination-absorber needs to be changed.

25 34. An elimination-absorber monitoring system kit having a sensor of claim 32 and a monitor/alarm unit that comprises:

30 a power source,
an alarm means,
an interlocking protruding or receiving portion corresponding with the portion on said monitor/alarm unit retainer,

35 a releasable sensor connector comprising a tab-receiving portion having two or more protruding contacts arranged to engage said conductive members, lateral surfaces for guiding and positioning said tab, and having means to deform said resilient support thereby retaining said tab portion while maintaining its orientation and pressure against said contacts to ensure continuous electrical connection of said conductive members with said contacts, and

40 electronic circuitry employing relatively narrow, relatively low duty-cycle pulses to measure conductivity or capacitance between a pair of spaced conductors or semiconductors that are disposed within or that span an appropriate measurement path

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relative to the elimination-absorber to be monitored and actuates said alarm means when the elimination-absorber needs to be changed.

5 35. A monitor/alarm unit for use with an elimination-absorber monitoring system, said monitor comprising:
 a power source,
 an alarm means,
 a releasable sensor connector, and
 electronic circuitry employing directly driven, relatively narrow, relatively low duty-
 10 cycle pulses applied directly across a pair of spaced conductors or semiconductors that are disposed within or that span an appropriate measurement path relative to the elimination-absorber to be monitored, to measure conductivity or capacitance therebetween and actuate said alarm means when the elimination-absorber needs to be changed.

15 36. The monitor/alarm unit of claim 35 wherein the sensor is not subjected by the monitor circuit to substantially any impressed voltage during the time between sensing pulses, so that the electrically charged ions in the material to be sensed can tend to return to their original random distribution between such pulses, and wherein the sensing pulses have relatively fast rise/fall-times substantially shorter than their widths.

20 37. The monitor/alarm unit of claim 35 wherein repetitive initiation of said alarm means when activated is relatively synchronous with said sensing pulses, or is related to the sensing signal repetition rate via a common master clock frequency from which the respective repetition rates are derived.

25 38. The monitor/alarm of claim 35 wherein the sensing pulses applied to connecting conductors of a sensor are connected in common with one side of the power source, so that complete disconnection of circuit power can be accomplished by a single additional contact to one of the sensor's connecting conductors or semiconductors.

30 39. The monitor/alarm of claim 35 further comprising:
 a waterproof case enclosing said power source, said alarm means, said electronic circuitry, said releasable sensor connector being fabricated as part of said case, said case having control surfaces with access for said alarm means and control means, said access
 35 being sealed by a thin, at least partially flexible membrane,

 visible alarm means comprising an electro-optical source disposed in a through-opening in said control surface, said through opening being sealed by a relatively thin, substantially optically-permeable covering,

40 audible alarm means comprising a shallow recess in said case disposed behind an audibly transmissive, relatively thin flexible membrane with said recess having a sound permeable, structurally supportive, relatively rigid, perforated bottom, said recess allowing said membrane to vibrate freely in response to acoustic pressure waves from the outermost

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vibrating member of an electro-acoustic transducer disposed within said case but whereby said bottom limits the maximum deflection of said membrane to within its elastic limit thereby protecting said membrane from mechanical damage without excessively attenuating the sound transmission from said transducer during intended operation, and,

5 control means disposed through a surface of said case that both changes and indicates the alarm or indicative function selected for the system's operation in response to actuation of said control means, where said indication is by means of activating the visible or audible alarm to emit a representative signal, said control means providing such indication only upon proper connection of an elimination-absorber sensor through said releasable
10 sensor connector.

40. An elimination-absorber monitoring system comprising sensing means and an electronic monitor/alarm unit releasably attachable to said elimination-absorber, said monitor/alarm unit comprising:

15 a power source, alarm means, electronic elimination-absorber monitoring means wherein said monitoring means actuates said alarm means when the elimination-absorber requires replacement, and wherein said alarm means comprises both an audible and a visible/silent indicative mode for purposes of alarm indication, and

20 single control means which, upon actuation, causes a change in said indicative mode employed by said monitor/alarm unit, from said audible to said visible/silent mode and vice-versa, and which, substantially simultaneous with actuation causes said monitor unit to produce either an audible or visible/silent representative alarm indication, said indication thereby demonstrating the mode selected and verifying said change.

25 41. The elimination-absorber monitoring system of claim 40, wherein said monitor/alarm unit further comprises attachment-controlled switching means whereby the on/off operation of said monitor/alarm unit and the switching of said power source are controlled by the mating or attachment of said monitor/alarm unit to said monitoring means.

30 42. The elimination-absorber monitoring system of claim 40, wherein said representative alarm indication further demonstrates or verifies the proper operable connection of said monitor to said sensor.

35 43. A fluid-sealed or contaminant-resistant audible signal transmission means for a case, enclosure, or panel of an electronic device, said means comprising:

40 a shallow recess in said case, enclosure or panel disposed behind an audibly transmissive, relatively thin flexible sealing membrane with said recess having a sound permeable, structurally supportive, relatively rigid, perforated bottom, said recess allowing said membrane to vibrate freely in response to acoustic pressure waves traveling either to or from the outermost vibrating member of an electro-acoustic transducer disposed within said device, but whereby said bottom limits the maximum deflection of said membrane to within its elastic limit, thereby protecting said membrane from mechanical damage without

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excessively attenuating the sound transmission to or from said transducer during intended operation.

44. A fluid-sealed or contaminant-resistant audible signal transmission means for a case, enclosure, or panel of an electronic device, said means comprising:

a sound permeable, structurally supportive opening in said case, enclosure or panel disposed behind an audibly transmissive, relatively thin flexible portion of a sealing membrane, said opening or a corresponding reduced thickness portion of said membrane allowing said membrane to vibrate freely in response to acoustic pressure waves traveling either to or from the outermost vibrating member of an electro-acoustic transducer disposed within said device, but whereby said opening limits the maximum deflection of said membrane to within its elastic limit, thereby protecting said membrane from mechanical damage without excessively attenuating the sound transmission to or from said transducer during intended operation.

45. A fluid-sealed or contaminant-resistant, high viewing/acceptance-angle optical signal transmission means for the case, enclosure, panel or the like of an electronic device, said means comprising:

an electro-optical source/detector having a relatively narrow beam exit/entrance angle, respectively, said source or detector being disposed within or behind a through-opening in said case, enclosure or panel, whereby said beam exit/entrance angle from/to said source or detector is substantially contained within said opening,

said through-opening being sealed by a relatively thin, substantially optically-permeable, relatively permanent covering,

said through-opening being further covered by a removable cover layer or flap of relatively thin, substantially optically-permeable material, whereby said removable cover layer acts to mechanically protect and help retain said case, enclosure or panel in a desired position while allowing the relatively unrestricted passage of said optical signal to or from said source/detector, and also whereby the presence and the optical properties of said cover layer or said permanent covering cause the useful viewing/acceptance-angle relative to said case, enclosure or panel to be substantially wider than said beam exit/entrance angle.

46. A test device for use with an elimination-absorber monitoring system, said system comprising: a sensor, and an electronic monitor/alarm unit releaseably connectable to said sensor, and said monitor/alarm unit comprising: a power source, an alarm means, a releasable sensor connector and electronic means to measure conductivity or capacitance between a pair of spaced conductors or semiconductors that are disposed within or that span an appropriate measurement path relative to the elimination-absorber to be monitored and wherein said electronic means actuates said alarm means when the elimination-absorber requires replacement, said test device comprising:

a support,

two or more conductive contacts disposed on said support whereby said contacts are

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releaseably connectable to said electronic means of said monitor/alarm unit by means of engagement of said support with said sensor connector,

5 a circuit disposed on said support and communicating with said contacts whereby the relative physical orientation of the support upon its engagement with said monitor/alarm unit substantially determines the conductivity or capacitance presented by said test device to said electronic means, said test device thereby simulating either a relatively unsoiled or soiled elimination-absorber, respectively.

10 47. The test device of claim 46 further comprising circuitry disposed on said support and communicating with said contacts whereby said circuitry connects said power source within said monitor/alarm unit upon engagement of said test device with said sensor connector regardless of which orientation of said test device is selected for said engagement.

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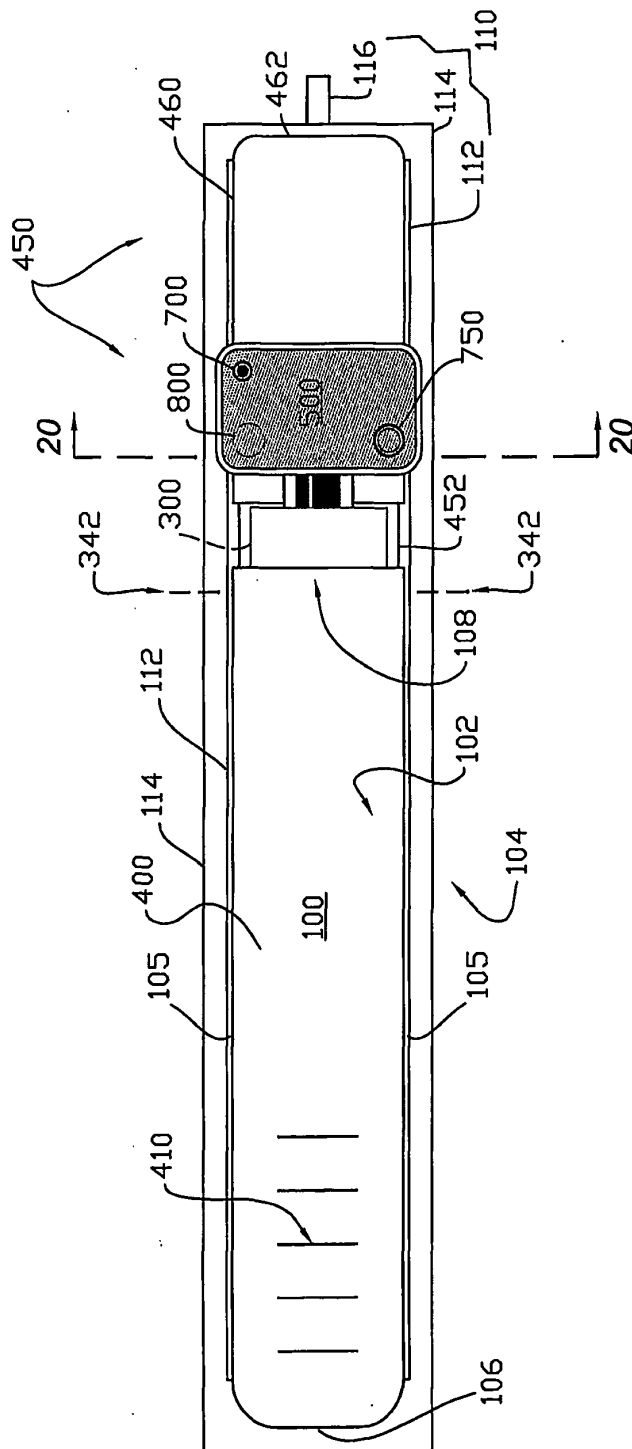


FIG. 1

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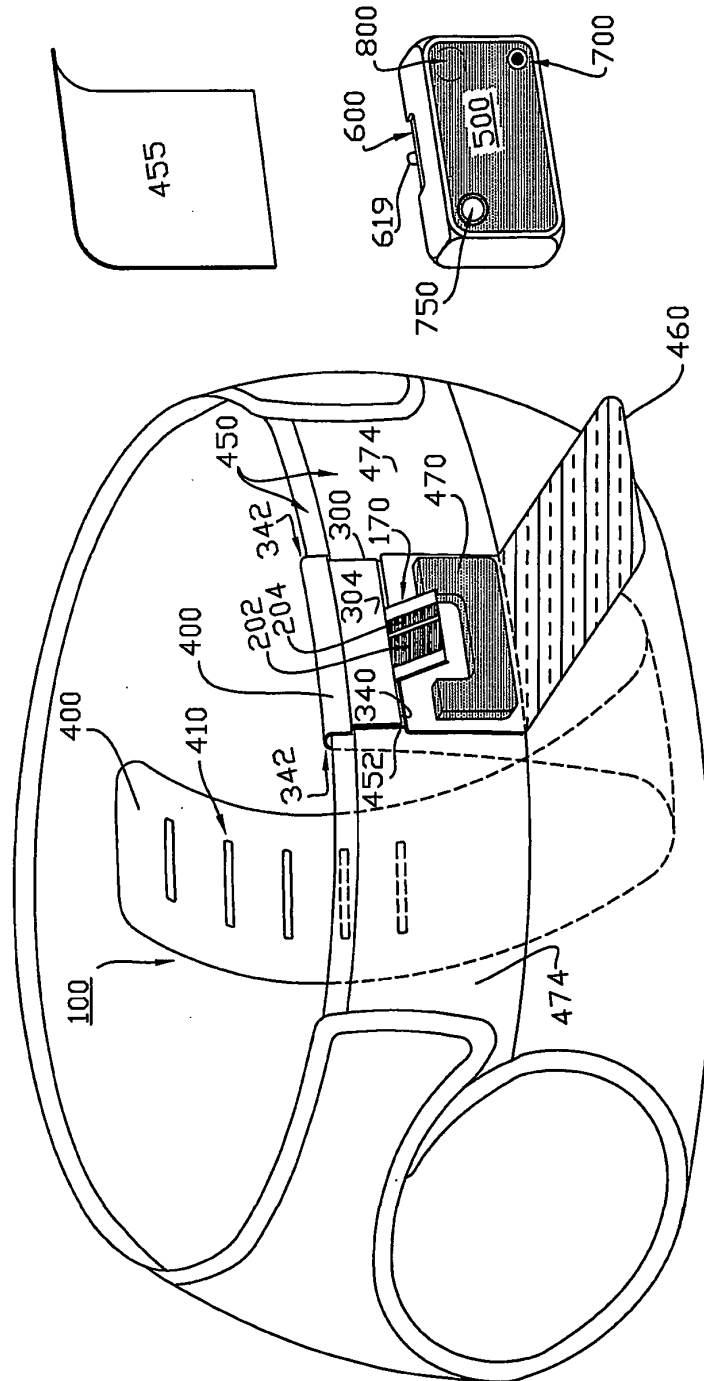


FIG. 2A

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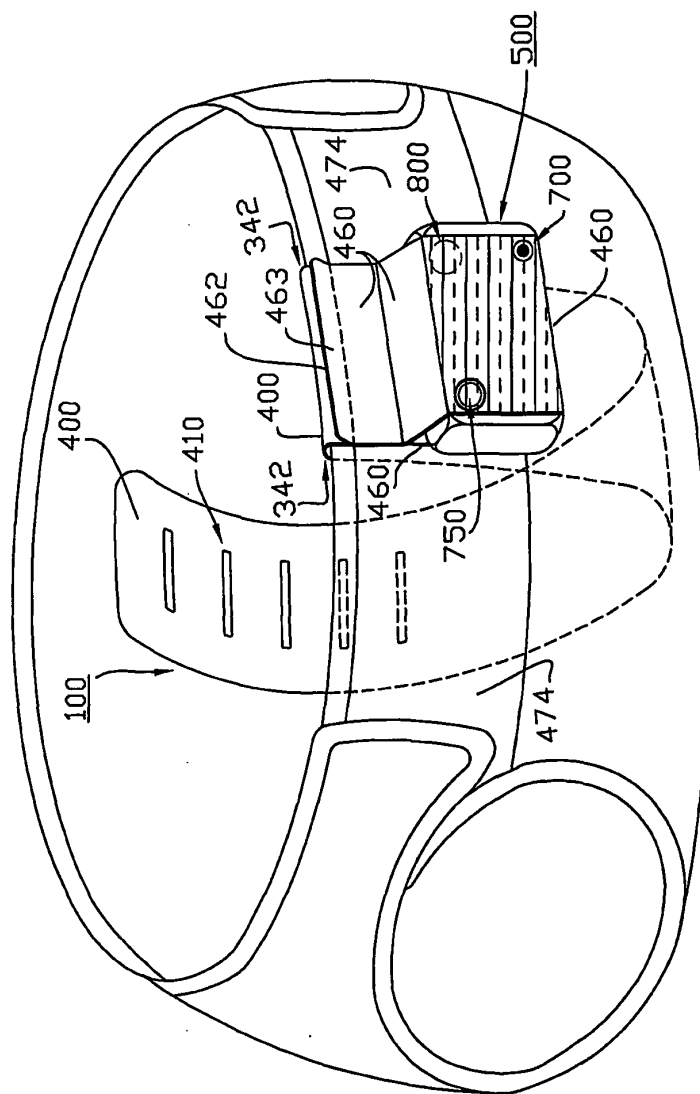


FIG. 2B

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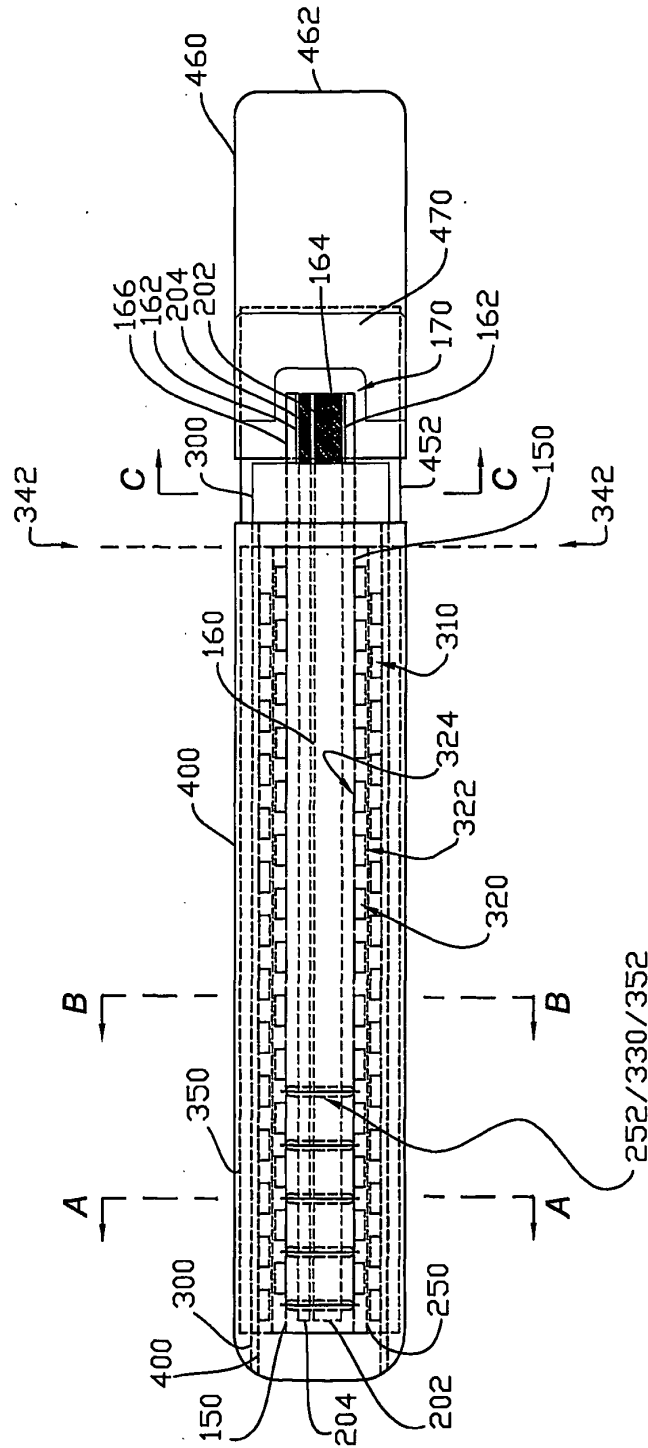


FIG. 3

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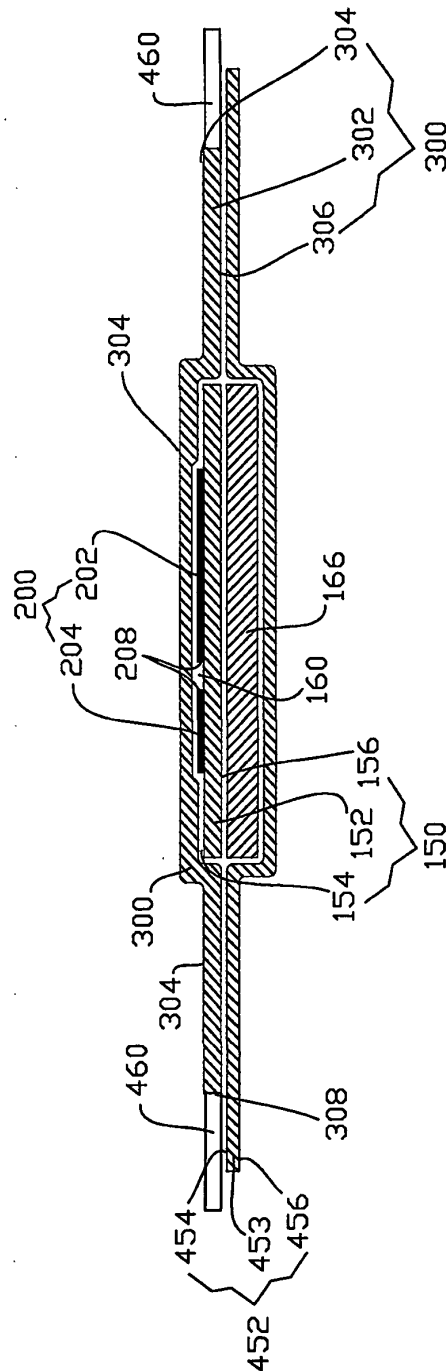


FIG. 3C

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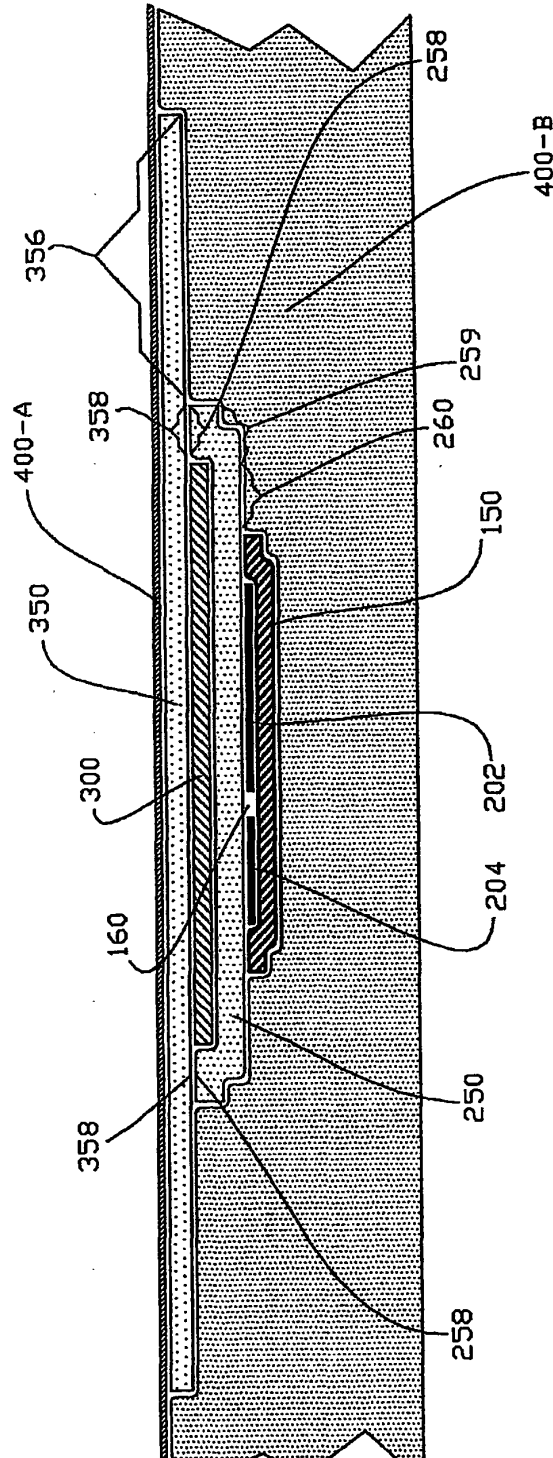


FIG. 3D

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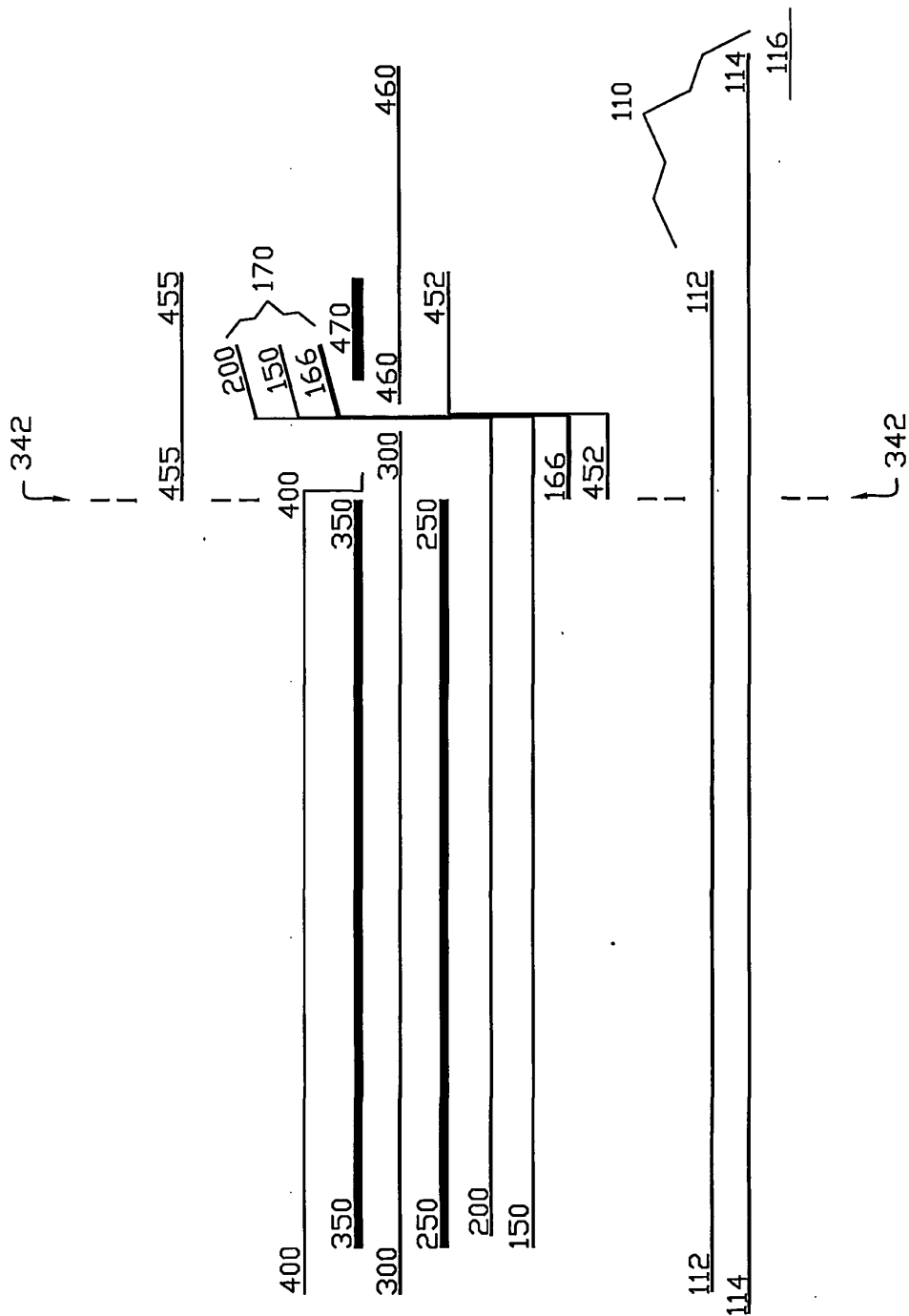


FIG. 4

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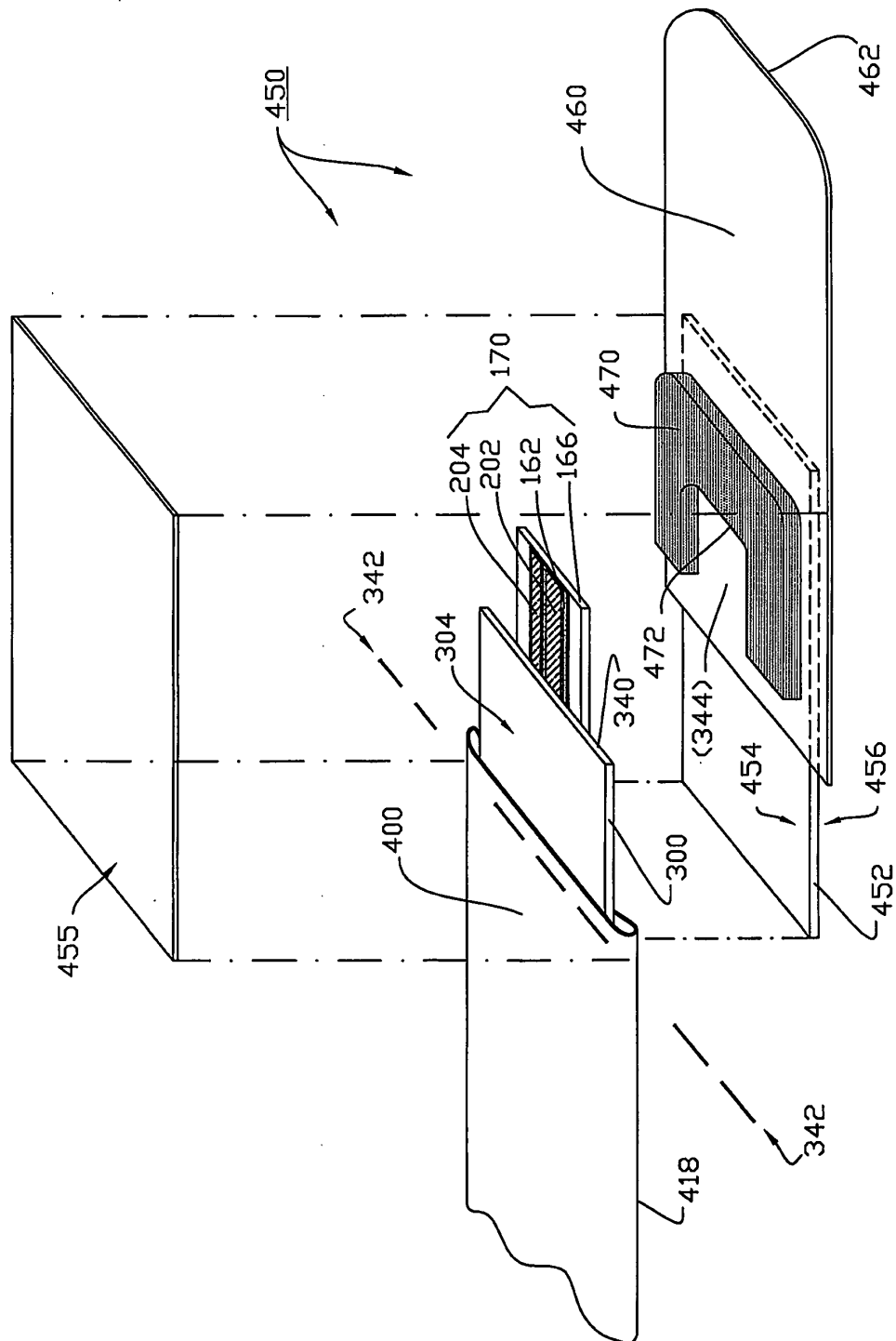


FIG. 5A

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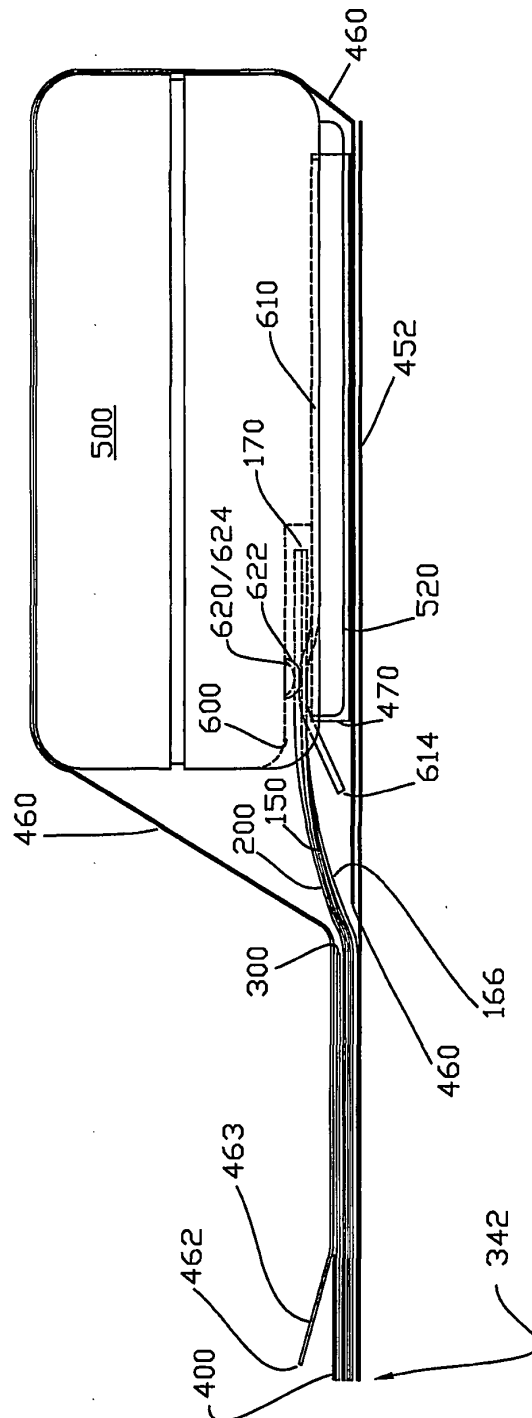


FIG. 5B

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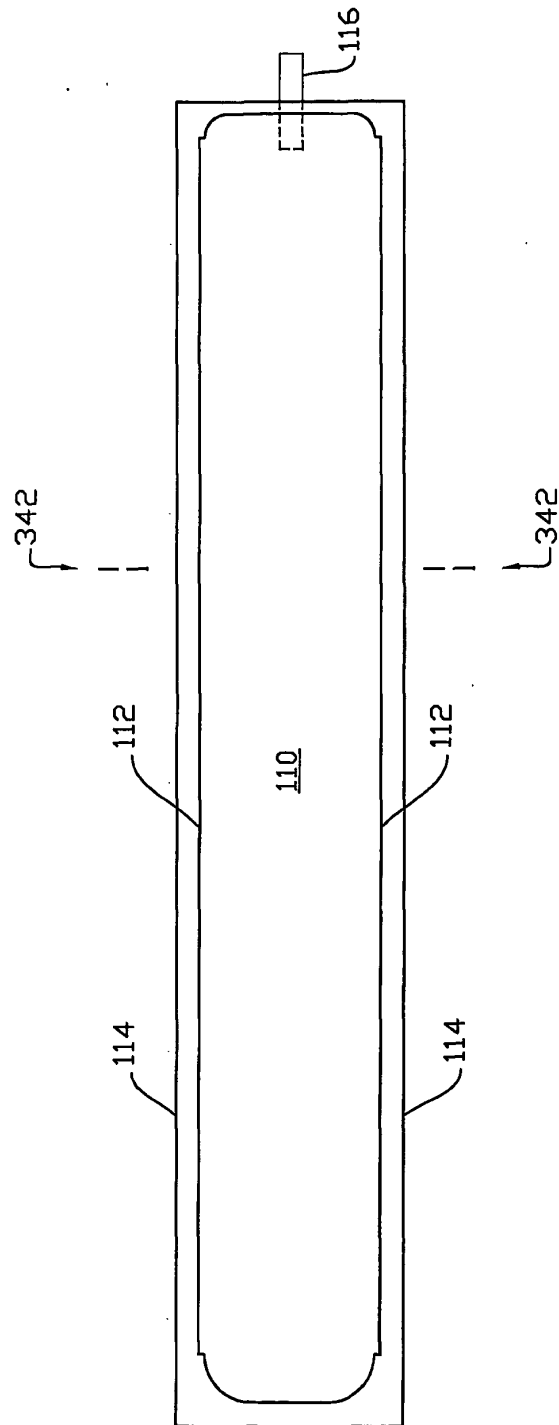
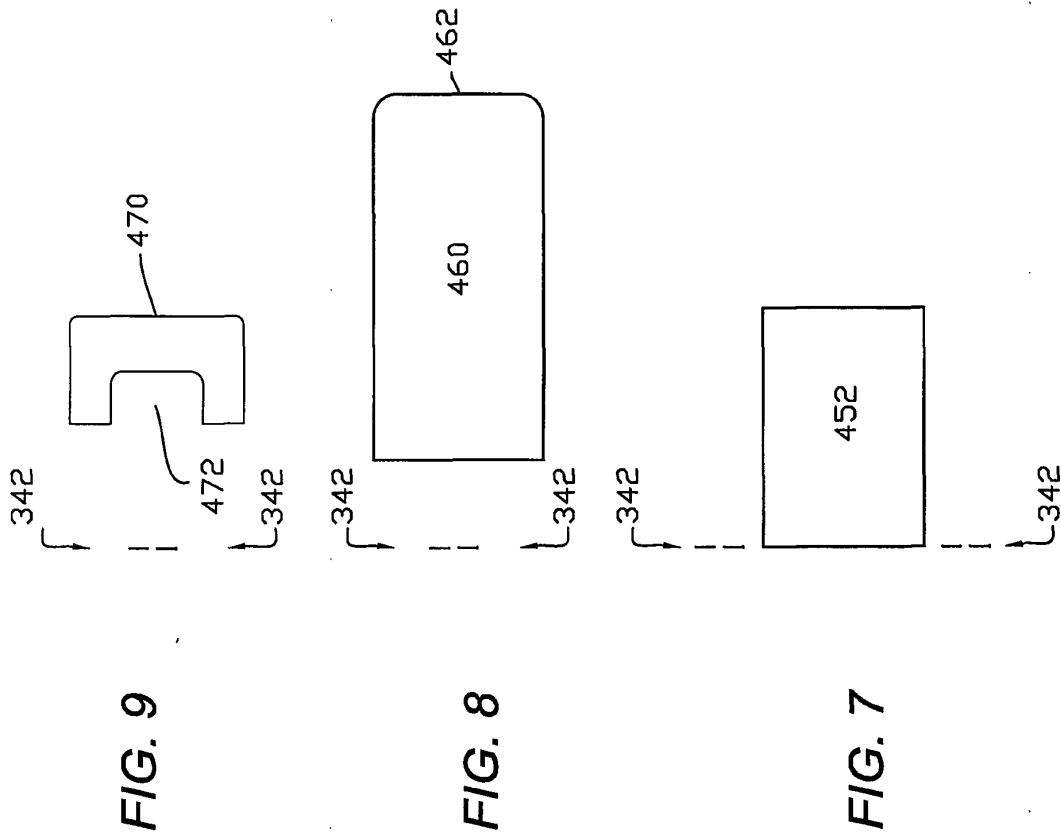


FIG. 6

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FIG. 12

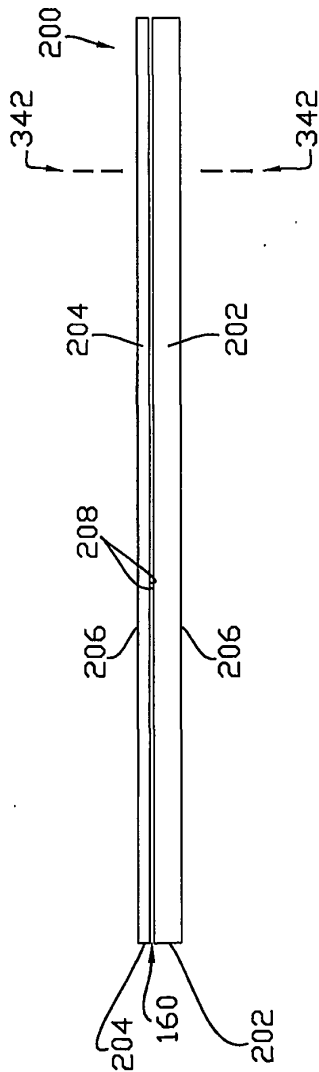


FIG. 11

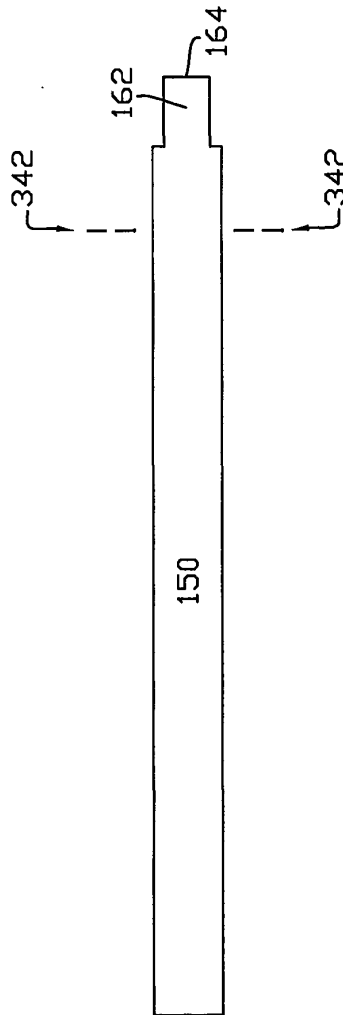
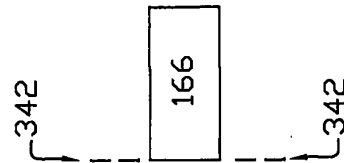


FIG. 10



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FIG. 14

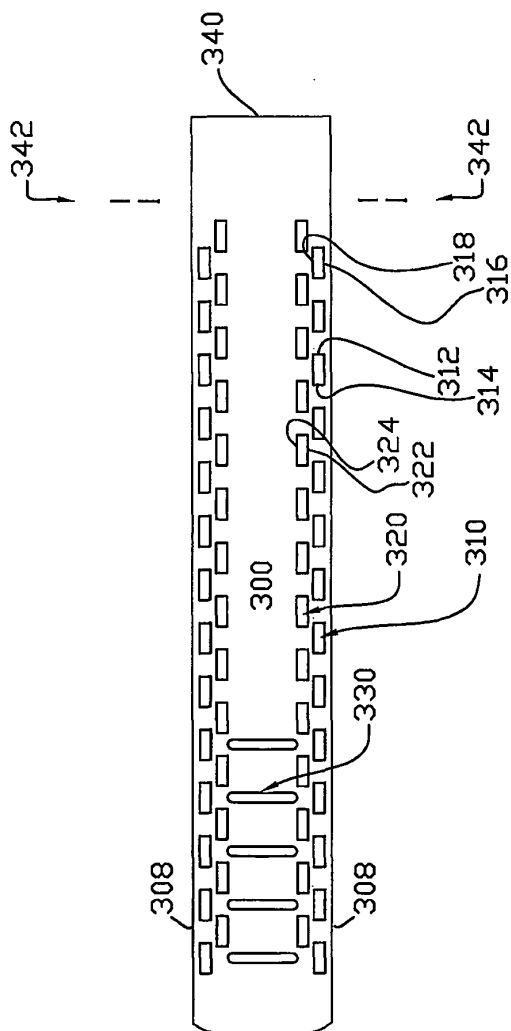
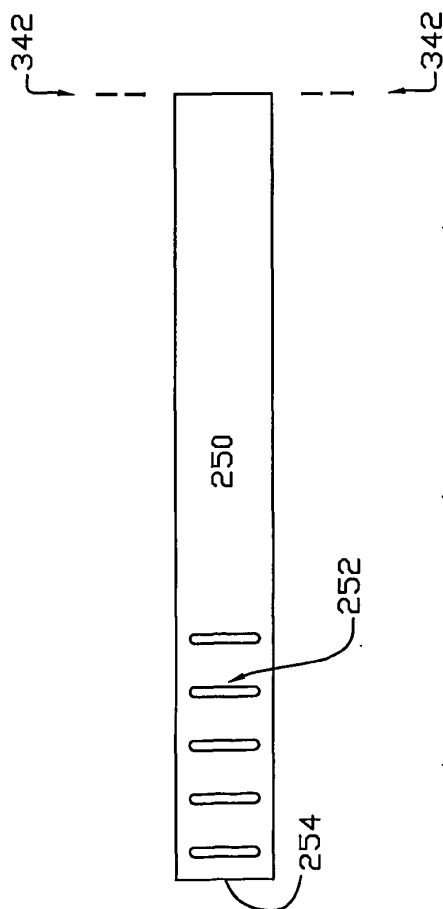


FIG. 13



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FIG. 17

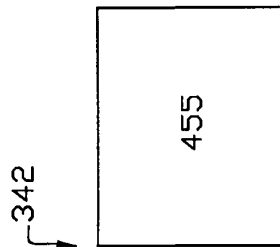


FIG. 16

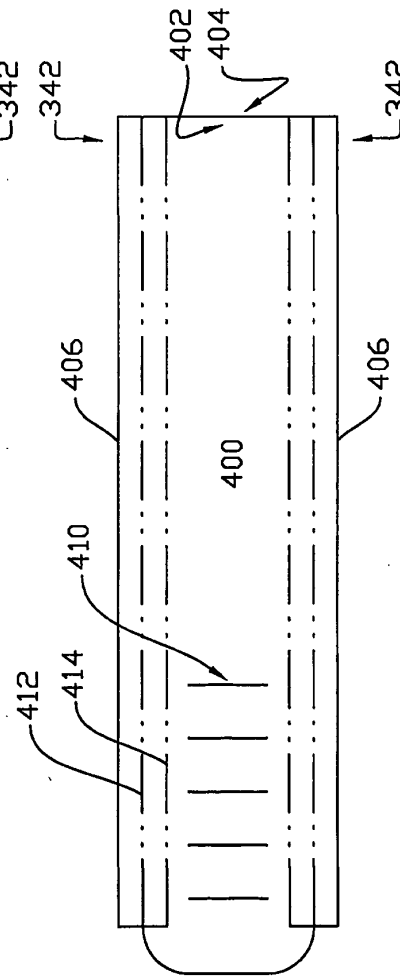
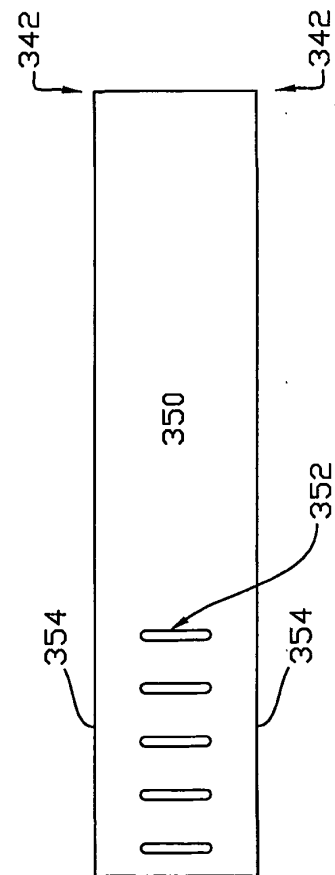


FIG. 15



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FIG. 18D

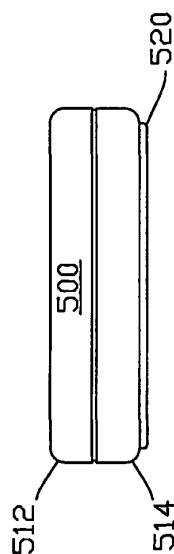


FIG. 18C

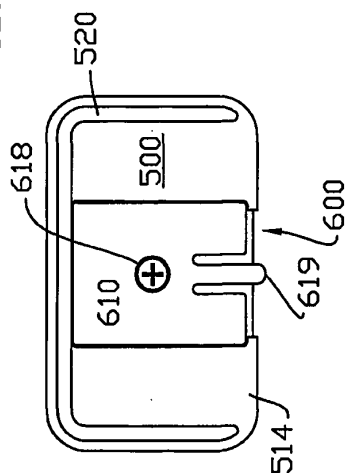


FIG. 18B

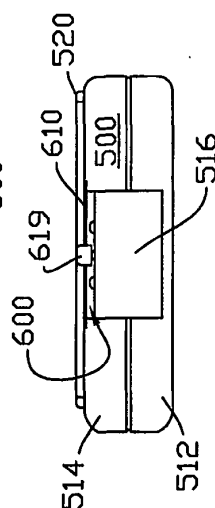


FIG. 18A

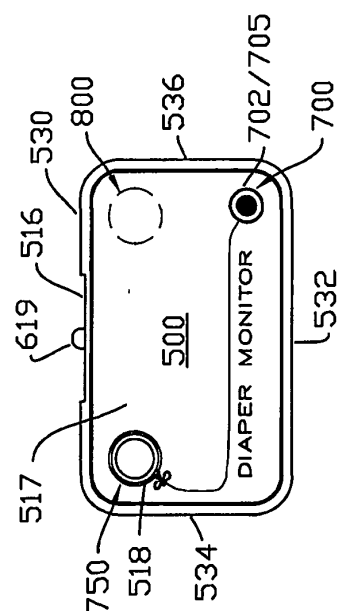


FIG. 19B

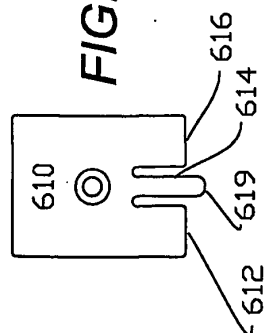
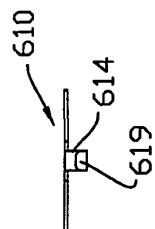


FIG. 19A



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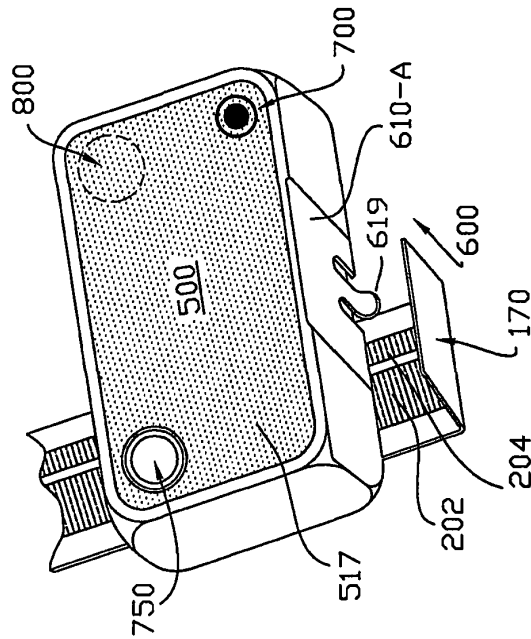


FIG. 21B

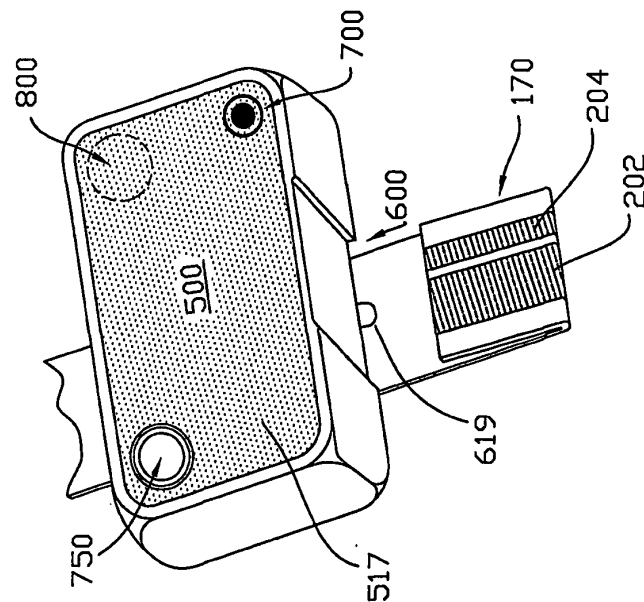


FIG. 21A

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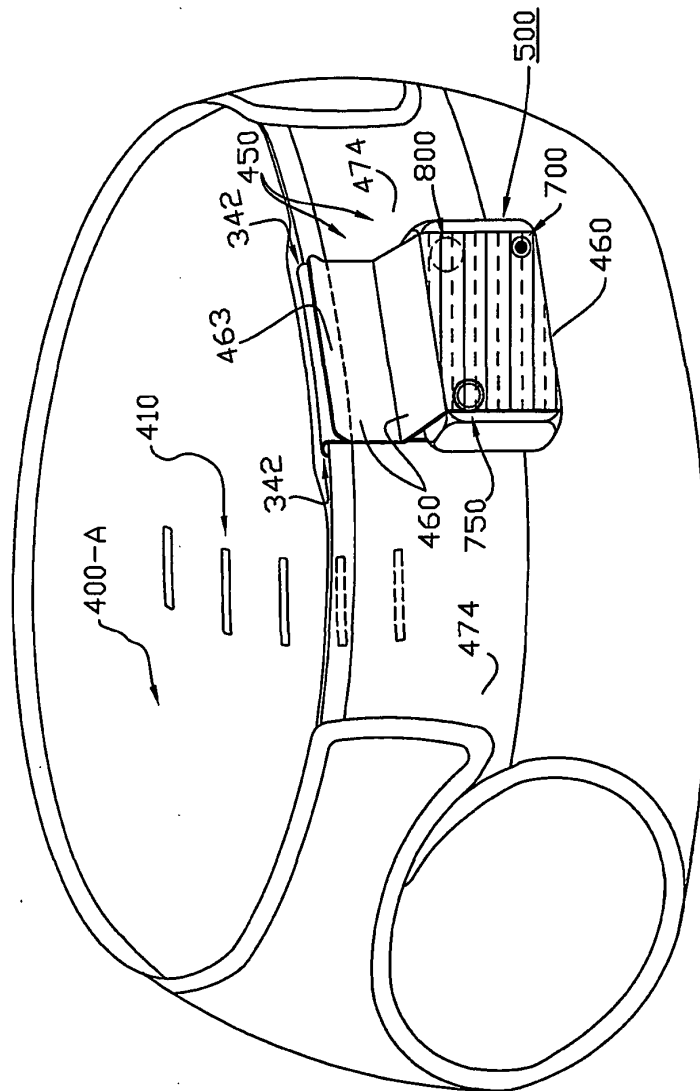


FIG. 22A

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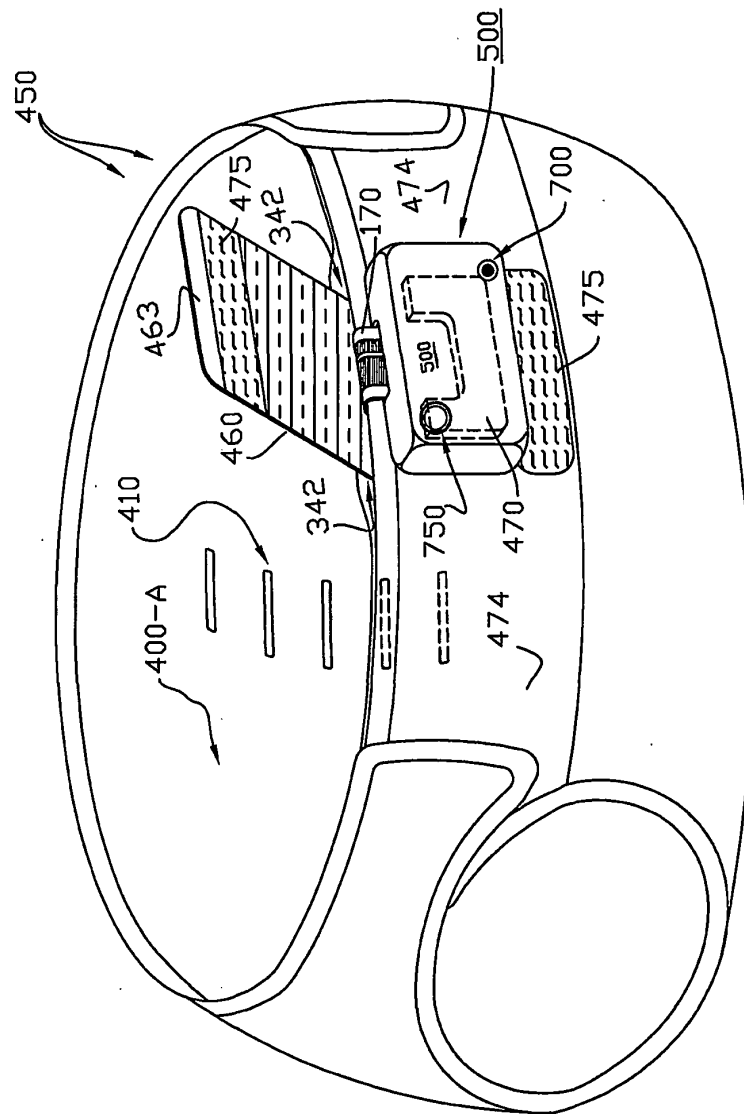


FIG. 22B

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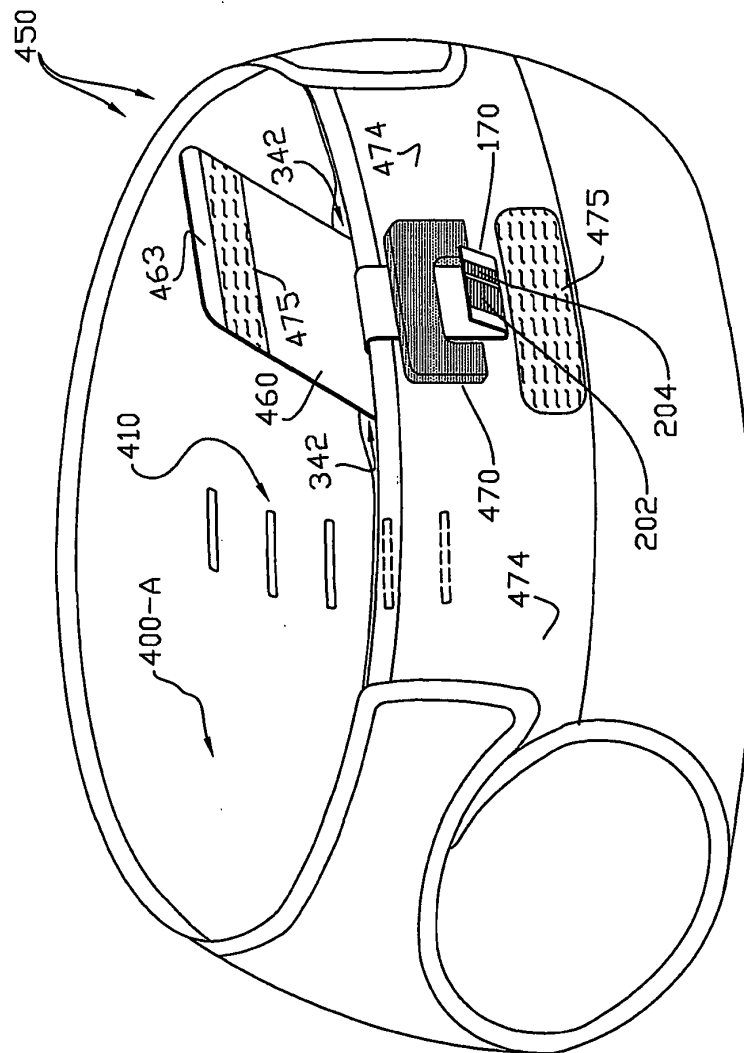


FIG. 22C

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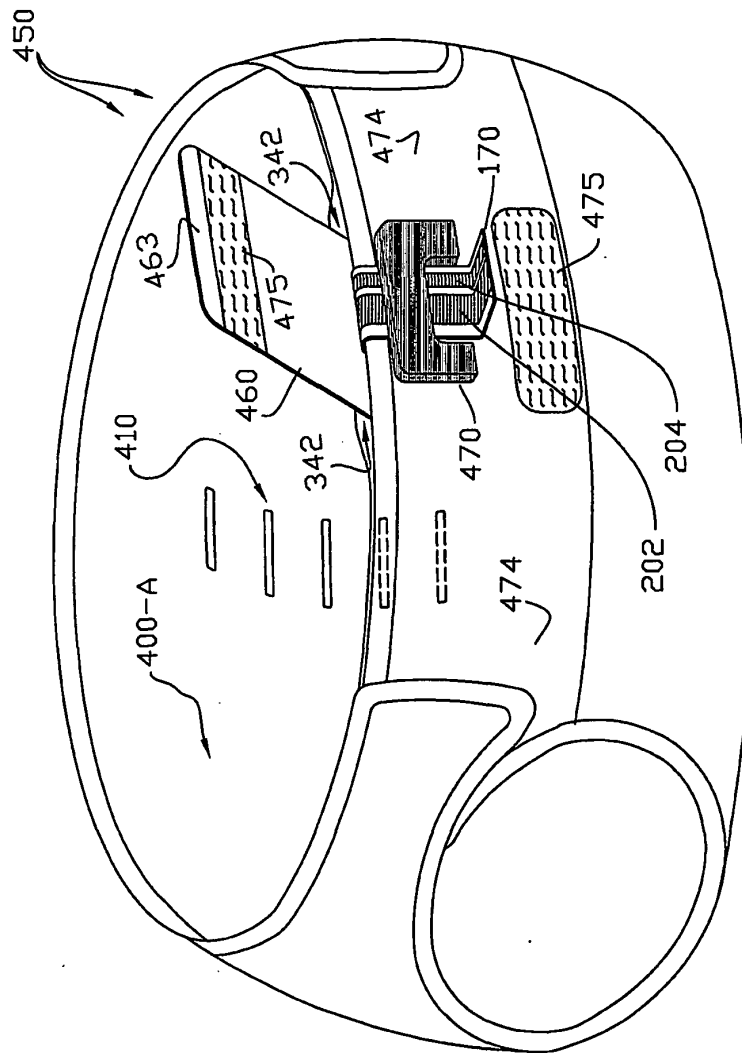


FIG. 22D

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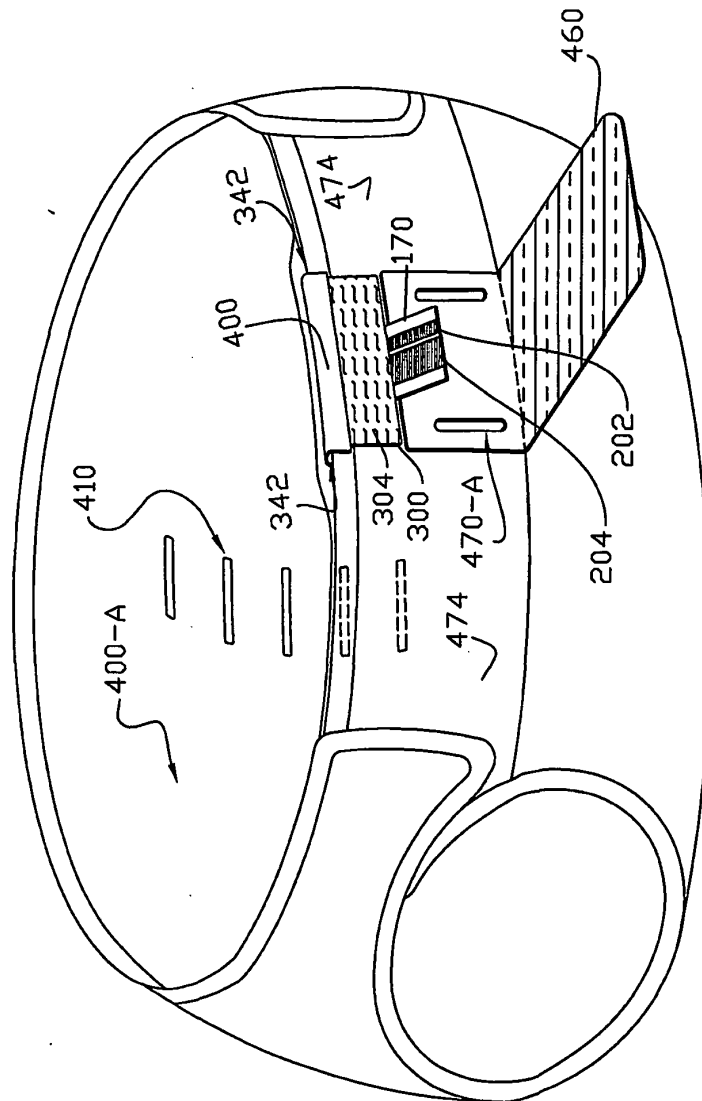


FIG. 22E

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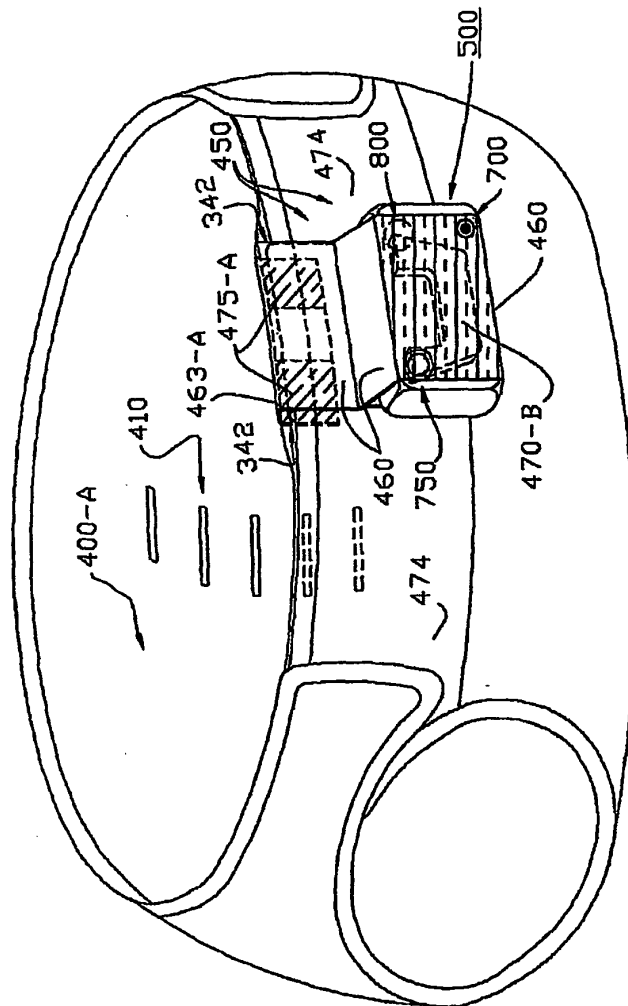


FIG. 22F

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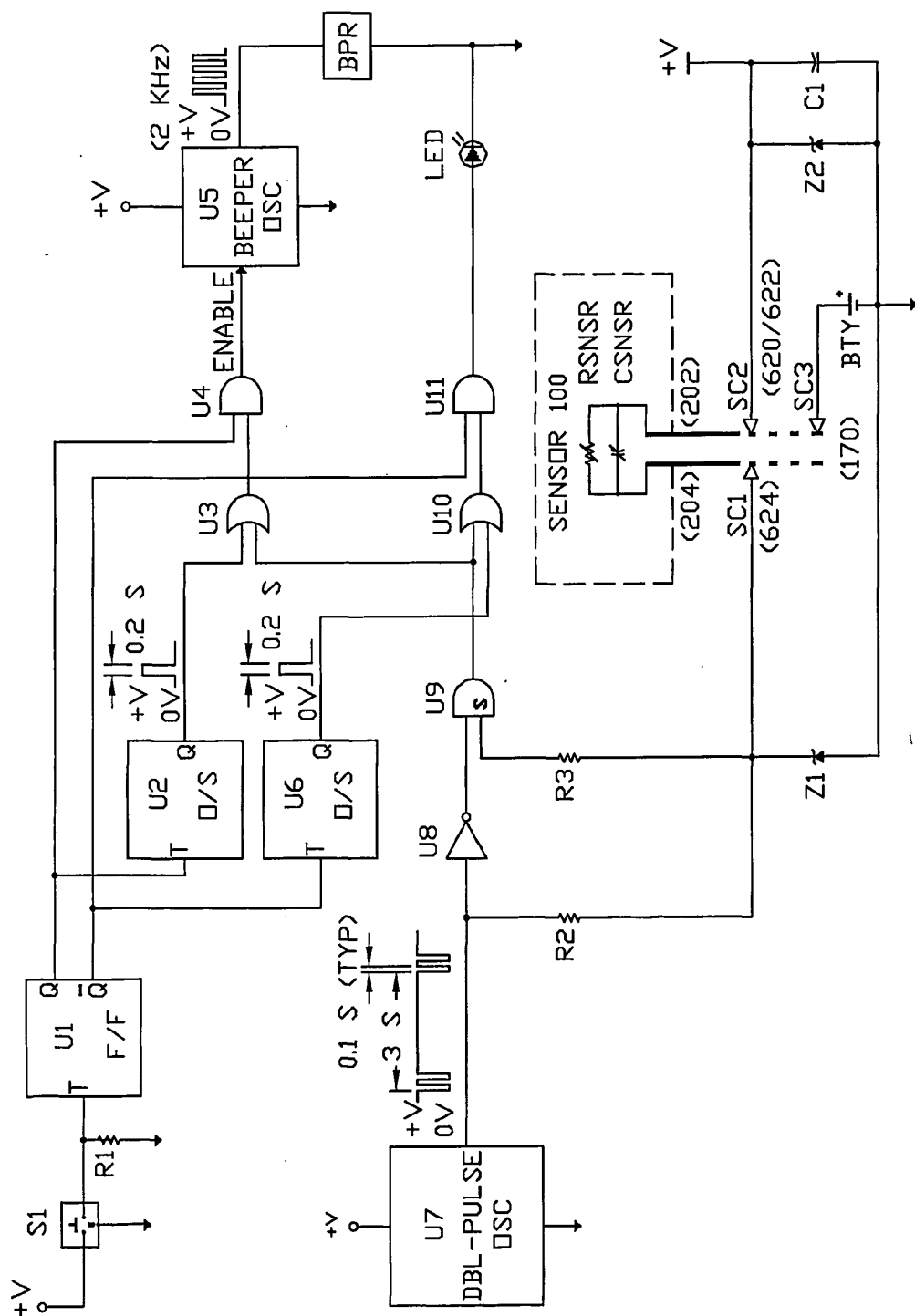


FIG. 23

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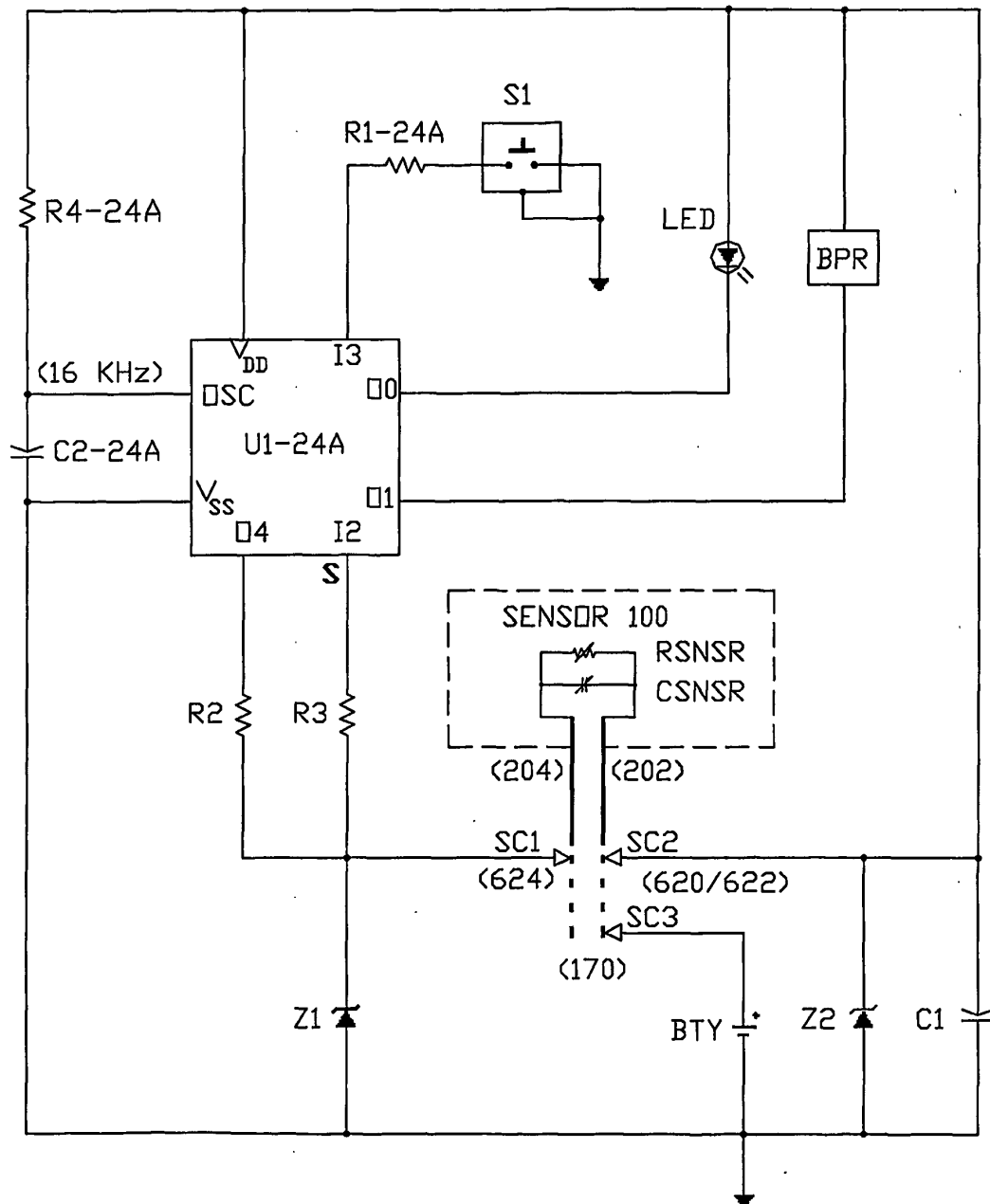


FIG. 24A

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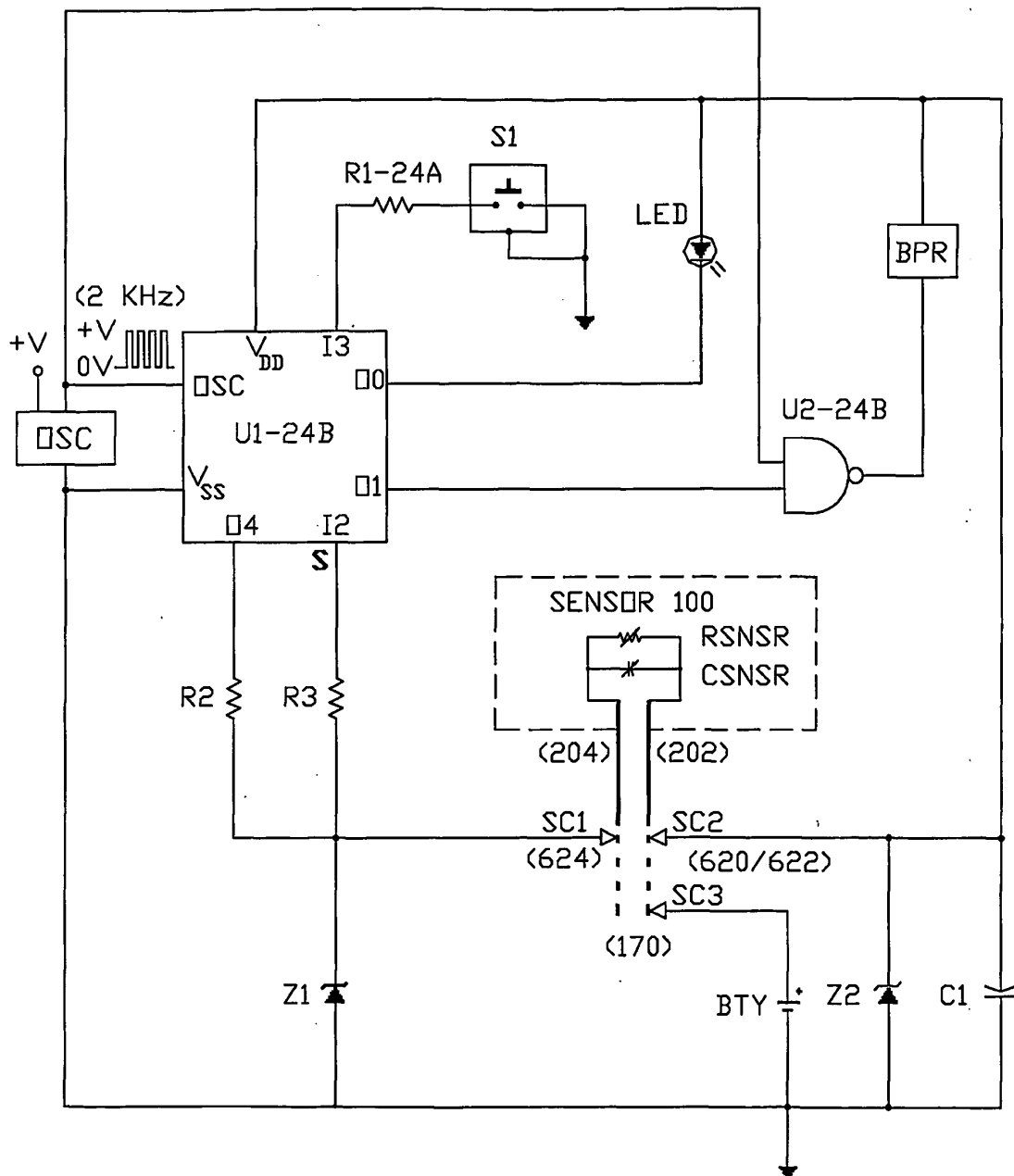


FIG. 24B

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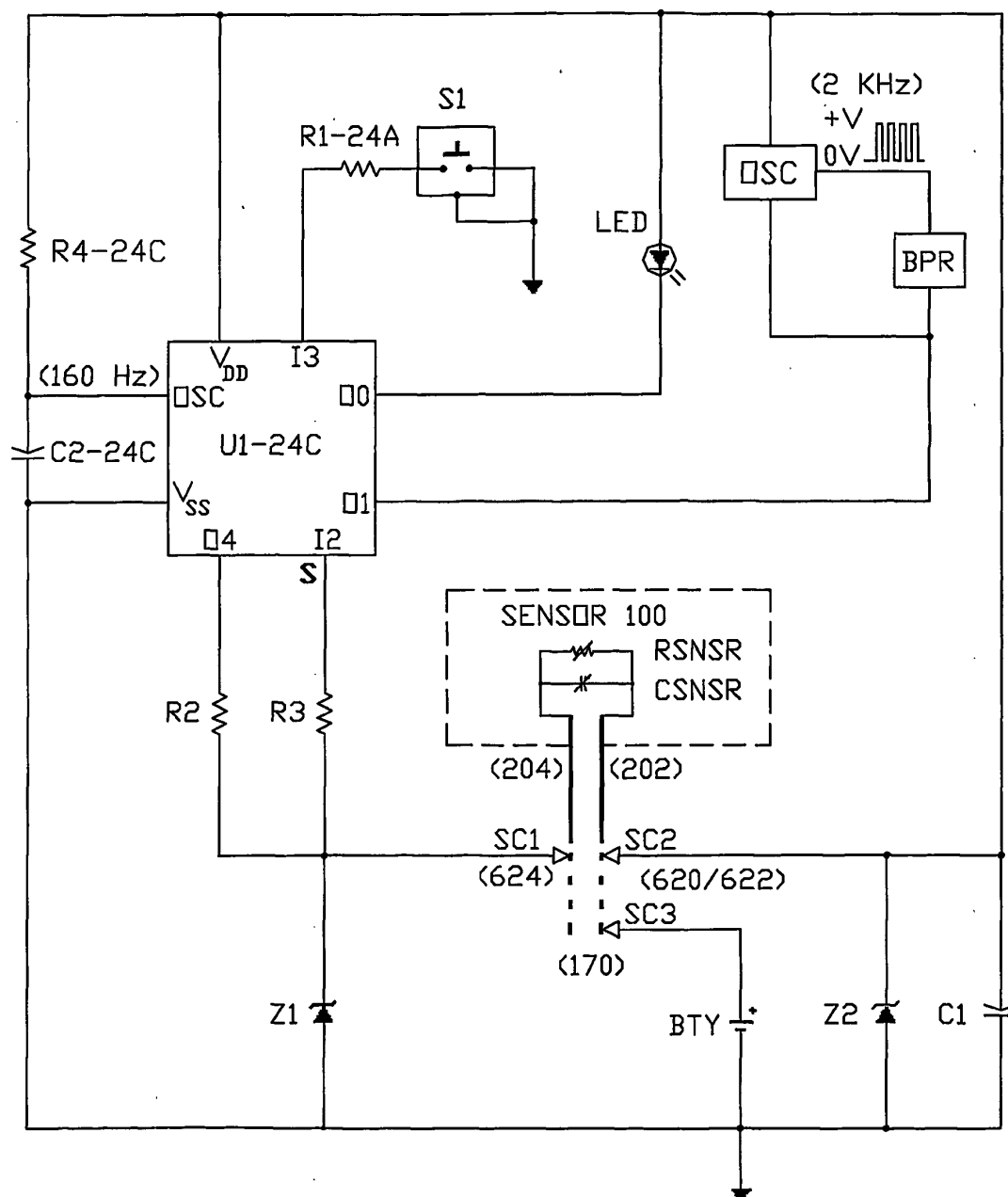


FIG. 24C

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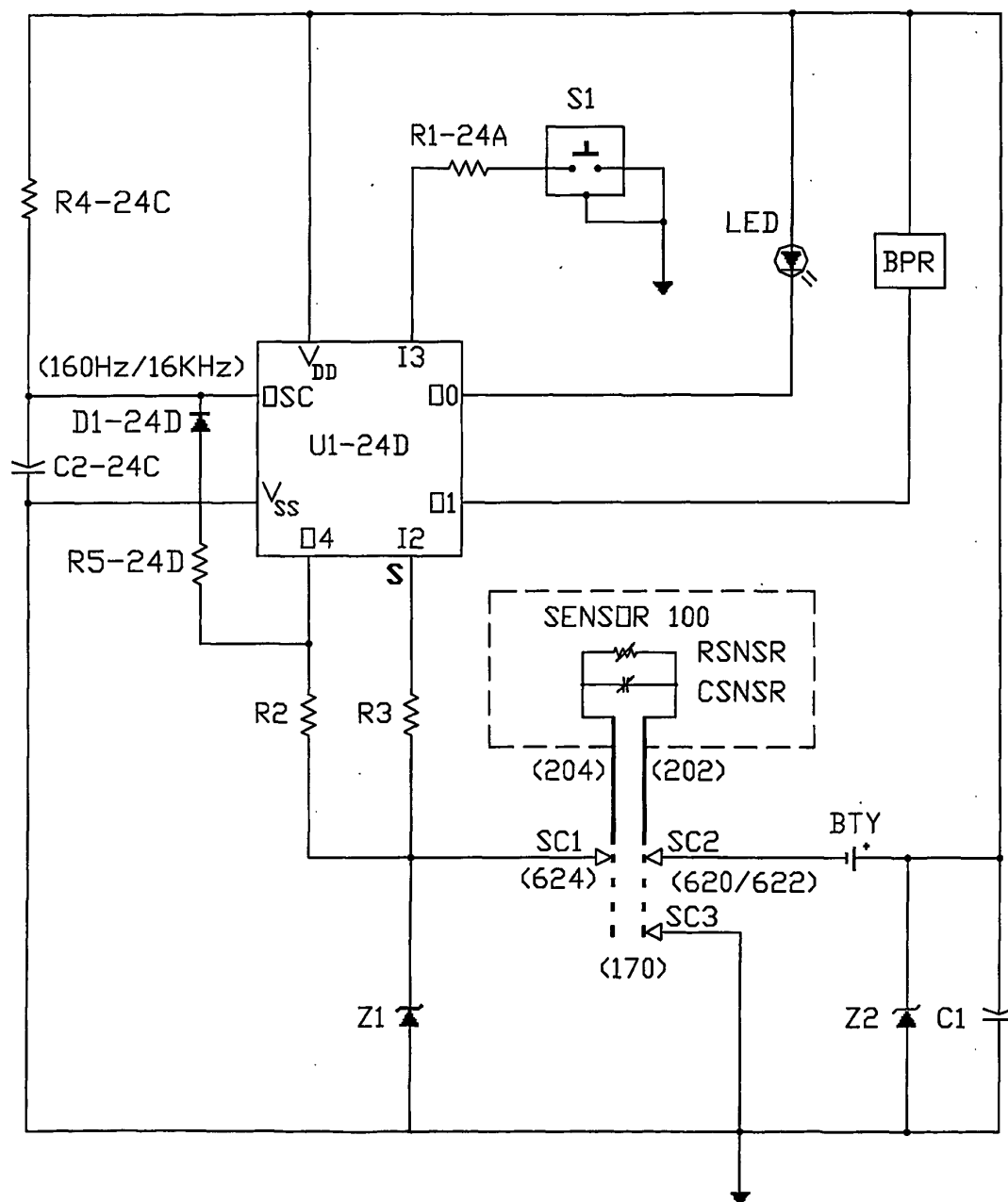


FIG. 24D

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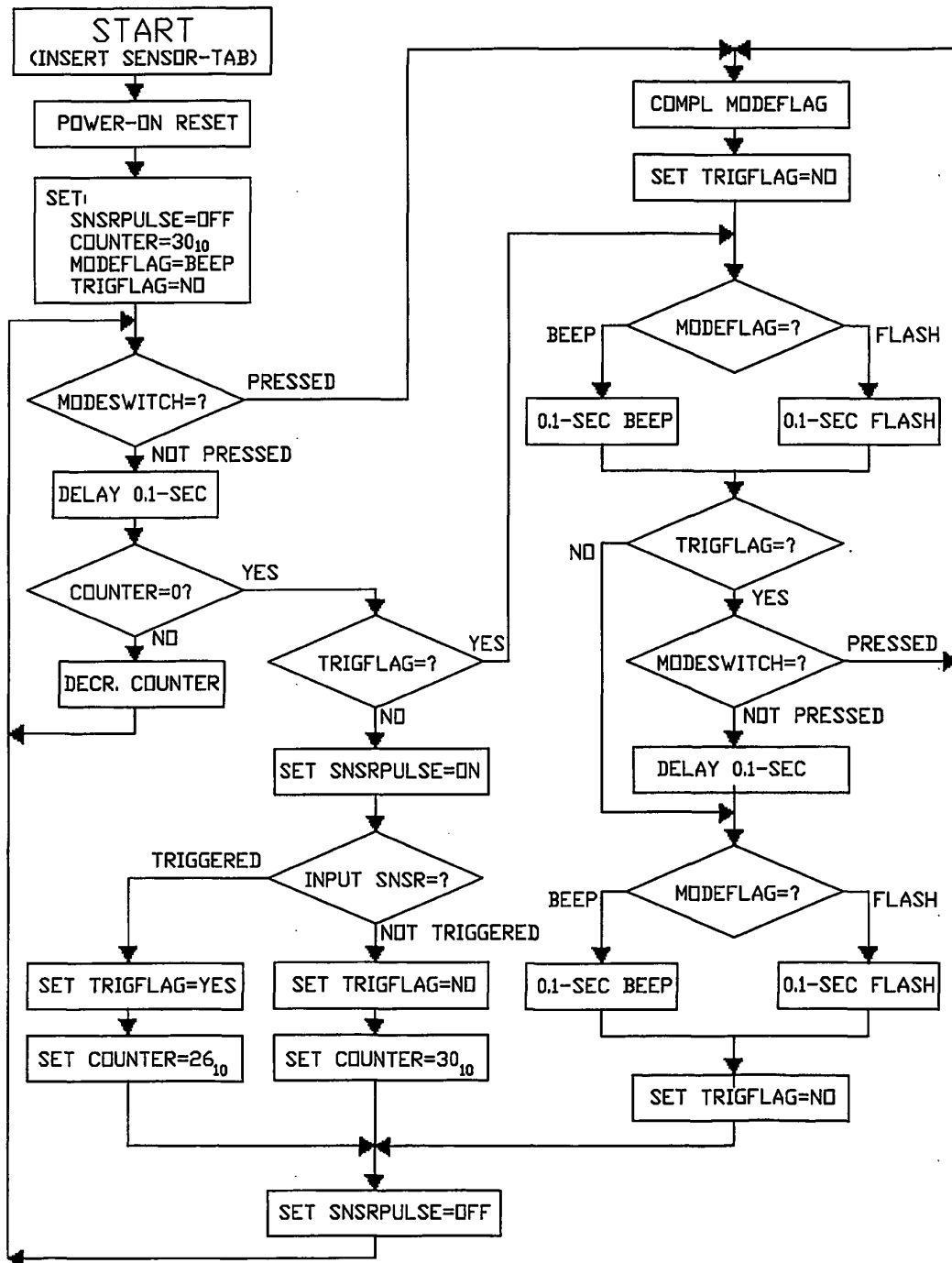


FIG. 25

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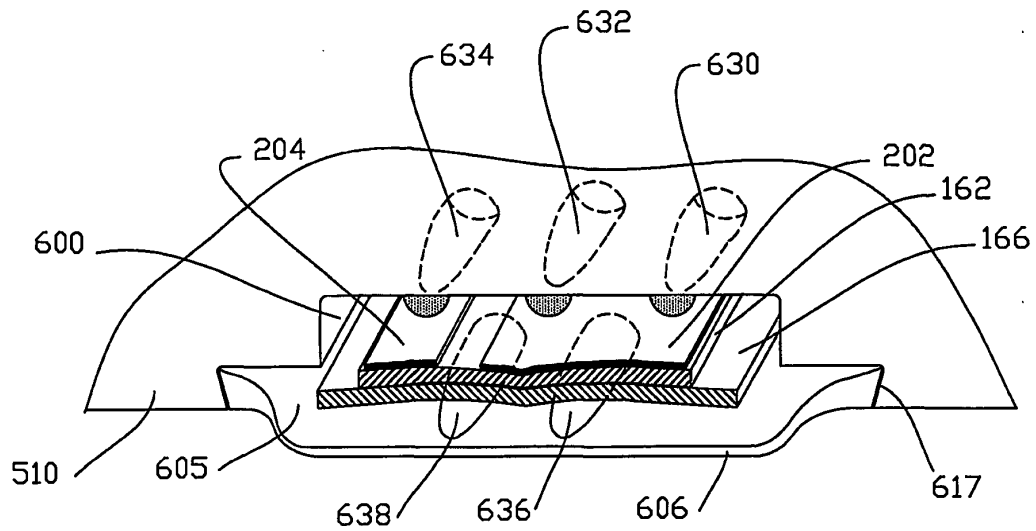


FIG. 26B

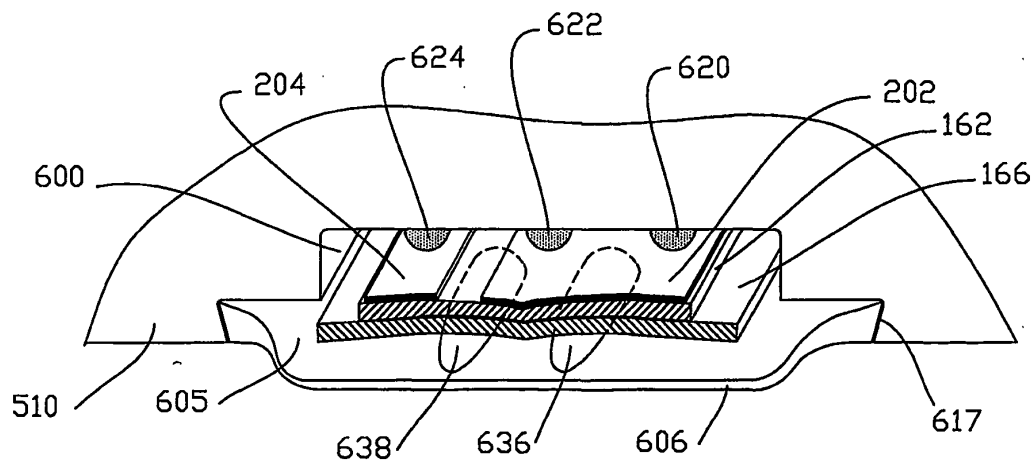


FIG. 26A

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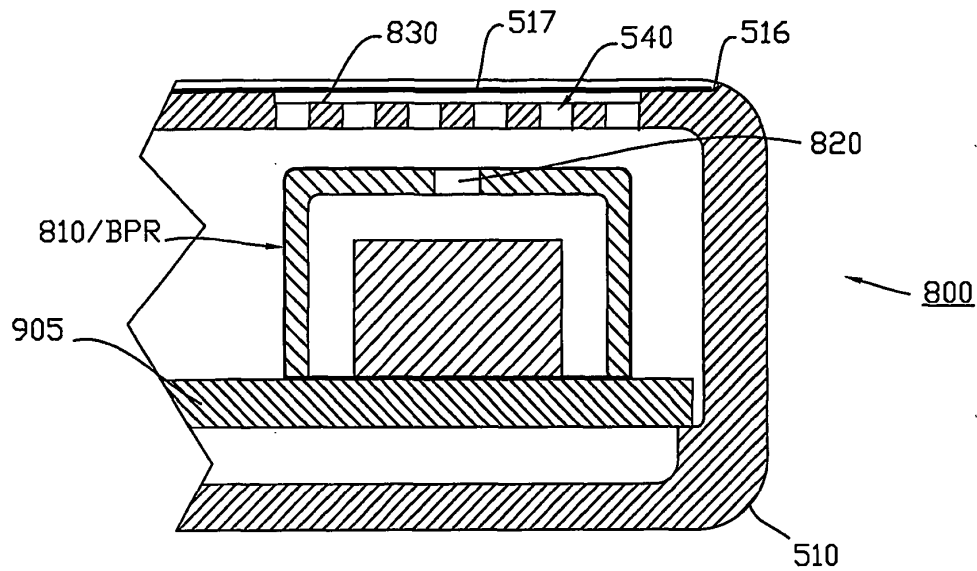


FIG. 28

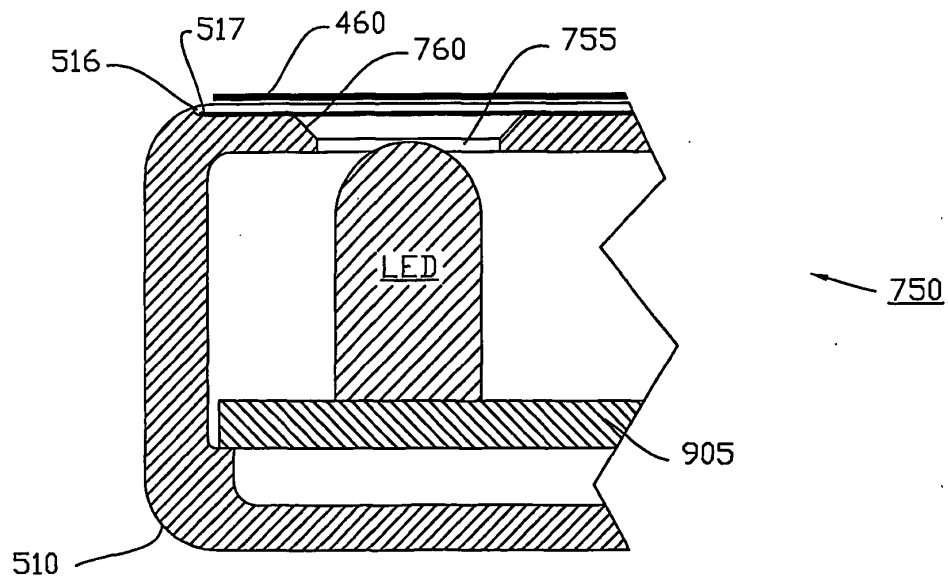
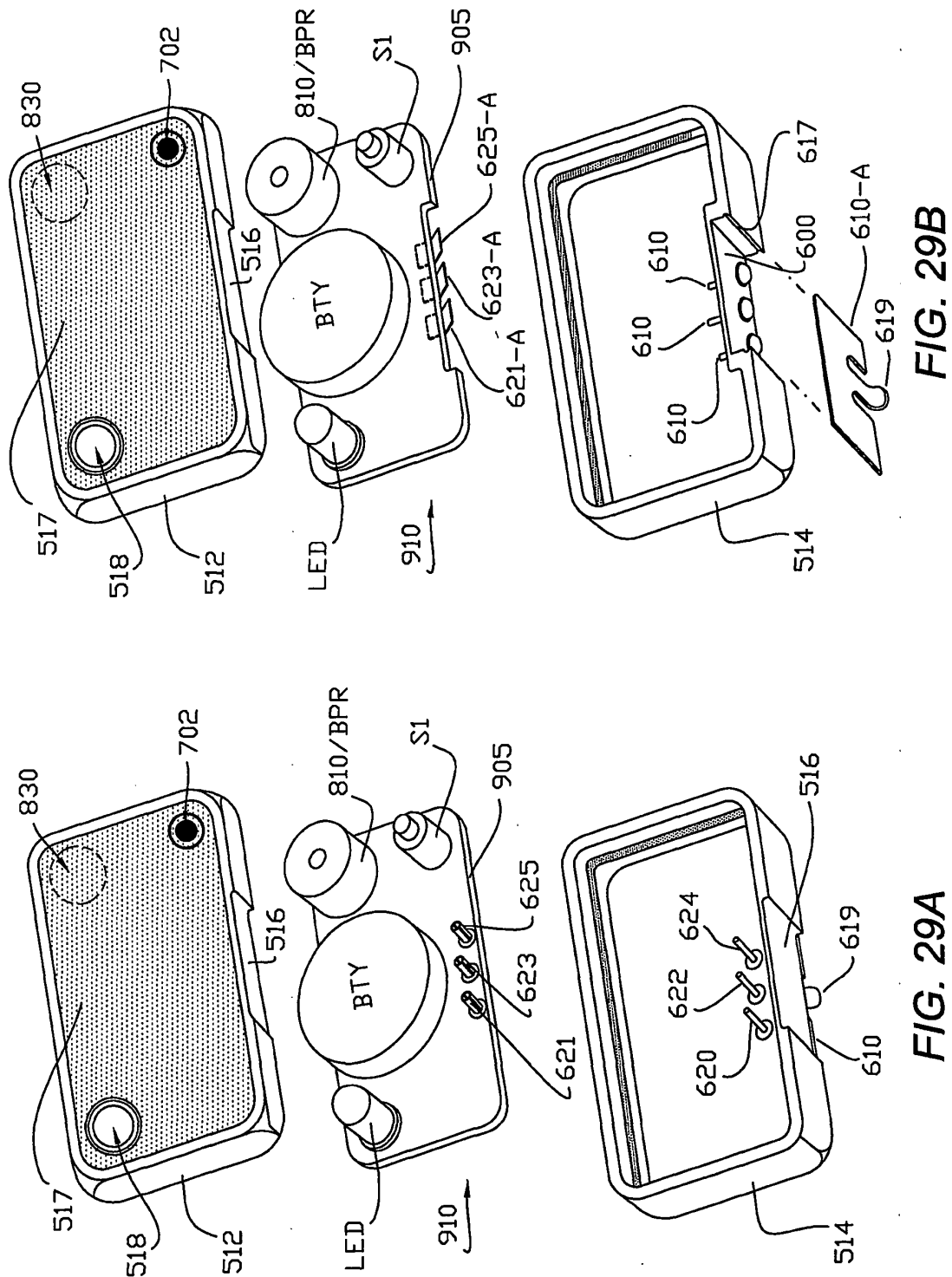


FIG. 27

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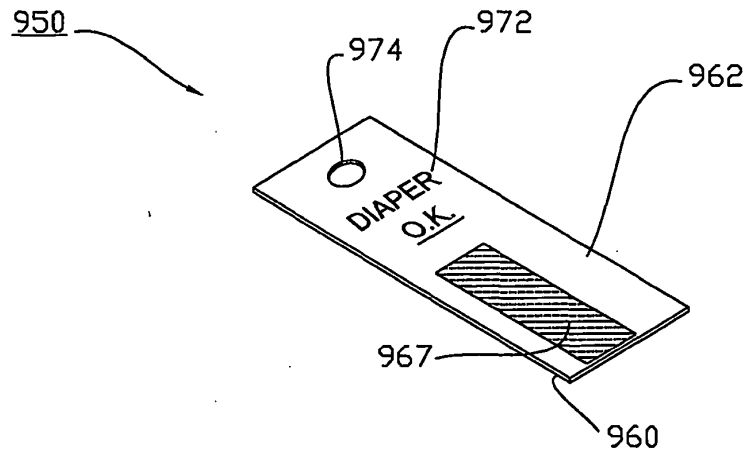


FIG. 30B

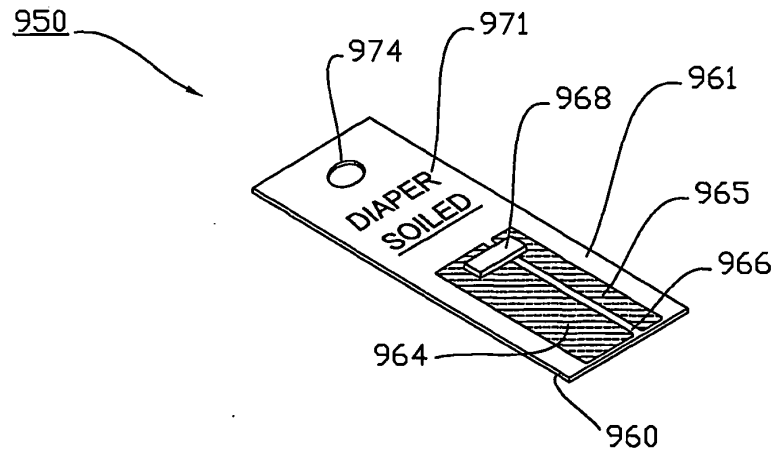


FIG. 30A

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G08B 21/00		A2	(11) International Publication Number: WO 97/42613													
			(43) International Publication Date: 13 November 1997 (13.11.97)													
(21) International Application Number: PCT/US97/08405		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TT, UA, UG, US, UZ, VN, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).														
(22) International Filing Date: 6 May 1997 (06.05.97)		<p>Published Without international search report and to be republished upon receipt of that report.</p>														
<p>(30) Priority Data:</p> <table border="0"> <tr> <td>08/646,453</td> <td>7 May 1996 (07.05.96)</td> <td>US</td> </tr> <tr> <td>08/665,199</td> <td>14 June 1996 (14.06.96)</td> <td>US</td> </tr> <tr> <td>08/663,686</td> <td>14 August 1996 (14.08.96)</td> <td>US</td> </tr> <tr> <td>08/700,011</td> <td>20 August 1996 (20.08.96)</td> <td>US</td> </tr> <tr> <td>08/773,343</td> <td>26 December 1996 (26.12.96)</td> <td>US</td> </tr> </table>				08/646,453	7 May 1996 (07.05.96)	US	08/665,199	14 June 1996 (14.06.96)	US	08/663,686	14 August 1996 (14.08.96)	US	08/700,011	20 August 1996 (20.08.96)	US	08/773,343
08/646,453	7 May 1996 (07.05.96)	US														
08/665,199	14 June 1996 (14.06.96)	US														
08/663,686	14 August 1996 (14.08.96)	US														
08/700,011	20 August 1996 (20.08.96)	US														
08/773,343	26 December 1996 (26.12.96)	US														
(71) Applicant (for all designated States except US): KNOX SECURITY ENGINEERING CORPORATION [US/US]; 1930 West Main Street, Stamford, CT 06902 (US).																
(72) Inventors; and																
(75) Inventors/Applicants (for US only): NISSIM, Ofer [IL/US]; 49 White Birch Road, Pound Ridge, NY 10576 (US). ELLINGHAM, Donald, B. [US/US]; 281 Ruane Street, Fairfield, CT 06430 (US). JANSZEN, David [US/US]; 504 East 63 Street, New York, NY 10021 (US).																
(74) Agent: STANGER, Leo; 382 Springfield Avenue, P.O. Box 1455, Summit, NJ 07901 (US).																
(54) Title: MOISTURE DETECTING DEVICES SUCH AS FOR DIAPERS AND DIAPERS HAVING SUCH DEVICES																
(57) Abstract																
<p>A pair of spaced electrodes within an area subject to wetness couple non-conductively with a sensor protected from wetness, and an alarm sounds in response to moisture decreasing the resistance between the electrodes. For example the electrodes project into the absorbent material of a diaper and extend along the inside of the diaper sheath opposite a pouch on the outside of the sheath. The pouch contains a sensor capacitively coupled to the electrodes.</p>																

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TITLE

MOISTURE DETECTING DEVICES SUCH AS FOR DIAPERS
AND DIAPERS HAVING SUCH DEVICES

FIELD OF THE INVENTION

5 This invention relates to devices for
monitoring wetness, particularly in diapers, and to
diapers containing such devices.

BACKGROUND OF THE INVENTION

10 Various methods and means have been developed
for monitoring moisture or wetness in diapers. The
purpose of such devices is to set off an alarm when a
diaper becomes wet. This permits a mother to tend to a
newborn infant or toddler. However such devices have
15 disadvantages in that they may require conductors to
pass mechanically through the diaper's plastic outer
sheath, may subject the skin of the wearer to direct
voltages from a voltage source, may be sensitive only
in a limited area, may accidentally respond to the
wearer sitting on a wet or metal bench or park slide,
20 or have other drawbacks.

SUMMARY OF THE INVENTION

25 According to an embodiment of the invention,
a pair of spaced electrodes within the area subject to
wetness couple non-conductively with a sensor protected
from wetness, and an alarm sounds in response to
moisture decreasing the resistance between the
electrodes. For example the electrodes project into

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the absorbent material of a diaper and extend along the inside of the diaper sheath opposite a pouch on the outside of the sheath. The pouch contains a sensor capacitively coupled to the electrodes.

5 The various features of novelty which characterize the invention are pointed out in the claims forming a part of this specification. Objects and advantages of the invention will become evident from the following detailed descriptions of embodiments
10 of the invention when read in light of the following drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an exploded view of a diaper embodying the invention.

15 Fig. 2 is a perspective view of Fig. 1.

Fig. 3 is circuit diagram of a sensor used in Figs. 1 and 2.

Figs. 4 and 5 illustrate an embodiment of a pouch in Figs. 1 and 2.

20 Fig. 6 is a plan view of the rear of an embodiment of a diaper with a pouch on the outside and containing a sensor.

Fig. 7 is an frontal elevation of the rear of the diaper, when opened, in Fig. 6.

25 Fig. 8 is a plan view of the rear of another

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embodiment of a diaper with a pouch on the outside and containing a sensor.

Fig. 9 is an frontal elevation of the rear of the diaper, when opened, in Fig. 8.

5 Fig. 10 is a perspective view of a sensor embodying the invention.

Fig. 11 is a block diagram of another embodiment of the invention.

10 Fig. 12 is a flow chart which illustrates the steps performed by the processor in Fig. 11.

Fig. 13 is a continuation of the flow chart in Fig. 12.

15 Fig. 14 is a block diagram of a chip that, according to an embodiment of the invention, serves in place of a circuit in Fig. 3 or the processor of Fig. 11.

Figs. 15A, 15B, and 15C illustrate the waveforms induced on the sensing circuit by the chip after current limiting by an external resistor.

20 Fig. 16 illustrates the pins of the chip in Fig. 14.

Fig. 17 illustrates the operation with a piezoelectric element as the only output.

Fig. 18 illustrates the operation with only

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an LED output.

Fig. 19 illustrates the operation with piezoelectric and LED outputs.

5 Fig. 20 illustrates the operation with an LED and external DC-powered output circuit.

Fig. 20A illustrates operation with an external DC-powered output circuit only.

10 Figs. 21A and 21B are exploded perspective views of a diaper conveying two embodiments of the invention.

Figs. 22A, 22B, 22C, and 22D are plan views of surfaces that bear electrode arrangements corresponding to several embodiments of the invention.

15 Figs. 23A and 23B are plan views of surfaces that bear electrode arrangements corresponding to other embodiments of the invention.

Fig. 24 is an elevation of an electrode arrangement corresponding to an embodiment of the invention.

20 Fig. 25 is an elevation of an electrode arrangement corresponding to another embodiment of the invention.

Fig. 26 is an elevation of an electrode arrangement corresponding to another embodiment of the

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invention.

Fig. 27 is a perspective view of an electrode arrangement corresponding to another embodiment of the invention.

5 Fig. 28 is a perspective view of an electrode arrangement corresponding to another embodiment of the invention.

Fig. 29 is a perspective view of a pocket with aspects embodying the invention.

10 Fig. 30 is a perspective view of a pocket with a further aspect embodying the invention.

Fig. 31 is a perspective view illustrating the folding of a sensor element to shorten its effective length.

15 Fig. 32 is a perspective view illustrating an apparatus for the removal of a coating from an area of coated film.

20 Fig. 33 is a perspective view illustrating an apparatus for the placement of the sensing electrodes onto a diaper backing sheet web.

Fig. 34 is a perspective view illustrating an apparatus for the removal of non-conductive fibers from a wire-wrapped yarn.

25 Fig. 35 is a sectional view illustrating an example of a module in a pocket on the back of a

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diaper.

Fig. 36 is a plan view of the frontal area of a diaper having a cloth-like backing sheet and a treated rectangular portion.

5 Fig. 37 is a sectional view through an area of cloth-like backing sheet containing a treated portion.

Fig. 38 depicts an ultrasonic apparatus for processing of the treated portion of Figs. 16 and 17.

10 Fig. 39 is a perspective view of a diaper produced by the process of the invention.

Fig. 40 is a schematic representation of a machine for constructing diapers.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

15 In the exploded view of Fig. 1 and the partially-exploded perspective of Fig. 2, a disposable diaper 100 embodying the invention includes an inner sheet 104 of a water-permeable film which overlies a wetness absorber layer 107 of powerfully liquid-
20 absorbent padding or other powerfully absorbent material. In one embodiment the layer 107 may include a gel-forming absorbent resin. An outer water-impermeable electrically-insulating plastic sheath 110 supports two conductive spaced-apart electrodes 114, in
25 the form of metallic or other electrically-conductive strips, that extend along the center of the sheath 110 and in electrical contact with the absorber layer 107.

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According to an embodiment of the invention, the electrodes 114 pass longitudinally through the layer 107. According to another embodiment, the electrodes 114 are in the form of conductive threads or wires.

5 The sheet 104 is common to most disposable
diapers and is often referred to as cover stock. It is
composed of thick porous, relatively hydrophobic,
bonded fibers which tend to pass liquid in one
direction from the wearer to the absorber layer 107.
10 The urine is held away from the skin by the competition
between the highly absorbent layer 107 and the not-so-
absorbent sheet 104. In this way the relatively
hydrophobic fibers space the wet mass of the layer 107
from the skin of the wearer. This keeps the skin dry
15 even when the wearer has wet the diaper. The sheet 104
may be omitted in training diapers that intend to make
the wearer uncomfortable when the diaper is wet. The
diaper is worn in the usual fashion.

 The electrodes 114 terminate in widened pairs
20 of adjacent fixedly spaced electrically-conductive pads
117 on each end. The pairs of pads 117 at each end are
printed on the sheath 110 or are bonded to the sheath
110 so they maintain a fixed position on the sheath 110
and so they are in intimate contact with the sheath.
25 According to another embodiment, the pads 117 are
otherwise deposited or applied, such as by selective
metallization, or carbonization using a laser. Bonded
to the outer face of the sheath 110, directly opposite
the pads 117 at each end of the sheath, are pouches
30 120. Each pouch 120 is adapted to receive a removable
sensor 124 having thin electrically-conductive
rectangular planar members or surfaces 127. Although

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two pouches 120 exist, only one pouch receives a sensor 124. When two pouches exist, the selection of the pouch which receives the sensor 124 depends upon the preferences, e.g. based on the comfort, of the user.

5 The position of each pouch 120 is such as to place the pair of planar members 127 on the sheath 110, directly behind a pair of the pads 117 without overlapping one member 127 with two of the opposing adjacent pads 117 or vice versa. One of the pairs of
10 pads or members is larger than the other to permit tolerance in placement.

 According to an embodiment, each pouch 120 is composed of or contains, in some portion, resilient material (not shown) to press the members 127 into
15 position against the sheath 110 when the diaper is worn. The members 127 do not electrically contact the pads 117, rather the sheath 110 separates the members from the pads. When a sensor 124 sits in the pouch 120, the pair of members 127 of the sensor 124, and the
20 opposing pair of pads 117 form two adjacent capacitors.

 According to an embodiment, the sides of the sensor 124 are tapered to facilitate insertion in the collapsed pouch. The faces of the sensor 124 may also be tapered.

25 As shown in Fig. 2, suitable fastening strips 130 secure the diaper in operable condition, and the sensor 124 is placed in the pouch 120 at the rear or front of the diaper. When a user wears and wets the
30 diaper, the liquid passes through the sheet 104 into the absorber layer 107 and to the sheath 110. The

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liquid then electrolytically short-circuits the electrodes 114. Hence the electrodes 114 operate as a conductive switch which is open, i.e. non-conductive, in a dry diaper and closed, i.e. conductive, in a wet diaper.

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According to another embodiment of the invention, the diaper contains only one pouch 120. The diaper may further comprise other accessories as may be necessary or desired, such as elastic electrodes for close fit to the wearer, tapes, tabs, snaps or the like for fastening the diaper in place upon the wearer, for example.

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The sensor 124 contains an oscillating voltage or pulse source, preferably one having a low duty cycle, which capacitively couples to the members 127 to the pads 117 using the sheath 110 as the dielectric medium, and an alarm device which responds to the source. The spaced electrodes 114 form a switch that remains open (non-conductive) when the diaper is dry. The sensor 124 is set so varying current from the source cannot pass through the open switch formed by the electrodes 114. When the diaper is wet, the electrolytic action of the urine in the diaper contacts the electrodes 114 and closes the switch, i.e. makes it conductive across the gap between the electrodes 114. The sensor 124 is set so varying voltage of the source then passes a current from the sensor 124 through the capacitor formed by one member 127 and the opposing pad 117, through one electrode 114 through the electrolytically conductive gap between electrodes to the other electrode 114, through the capacitor formed by the second of the pair of pads 117 and the second of

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the pair of members 127, back to the sensor. The resulting current triggers an alarm which, according to one embodiment, energizes a piezoelectric sounder and plays a tune or makes some other sound such as a beep.

5 According to another embodiment, the alarm takes the form of a blinking or turned on light, such as an LED. According to another embodiment, the alarm is transmitted by radio waves, infra-red radiation, or other means to a remote position where an attendant can
10 monitor a number of children or other wearers.

 The alarm, in the form of a sound or light, informs the wearer, who may be an infant being trained, or the infant's parent, that the diaper is becoming wet. This allows prompt action. A sound or light
15 alarm may for example make the infant in training associate its urges with its training needs. The sound or light can also serve to notify an infant's parent that the child's diaper needs changing. A sound or
20 light alarm can inform a toddler's attendant of these needs. A sound alarm can be an aid in enuresis training. A light alarm can also warn an elderly incontinent or handicapped person without sensation in the peritoneal area of an incident, or inform a
caregiver of the need for changing.

25 The sensor 124 sets an alarm threshold sufficiently high to prevent a false alarm when a wearer sits on a metal bench or on a wet surface. The capacitive impedance between the pads 117 and members
30 127 is far less than that between the electrodes 114, even when the electrodes 114 are in the vicinity of

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metal or a wet surface. Thus the electrodes 114 present a high impedance unless shorted electrolytically by urine in the diaper. The sensor threshold is sufficiently high to avoid responding to the
5 capacitive coupling between the dry electrodes 114, and yet low enough to respond to the electrolytic conduction between the electrodes 114.

Sensing electrodes 114 are made to have such a small surface area that the amount of capacitive
10 coupling between sensing electrodes 114 and any items placed opposite them in contact with the outer surface of backing sheet 110 will be so small that the amount of current shunted to such external items will not be detectable by detector module 124. As a consequence,
15 the alarm will not be activated as the result of conditions external to the diaper 100, but only due to electrolytic conduction between the sensing electrodes 114. An example of an external item that might be placed against the outside of a diaper is a metal chair
20 that a wearer sits on.

Details of electrical portions of one embodiment of sensor 124 appear in Fig. 3 which includes a low duty-cycle pulser 300. In the pulser
25 300, an oscillator 304 and divider counter 307, forming part of an integrated circuit or chip, provide the time base for all events in the wetness detection process. In one embodiment, the counter 307 yields a low frequency pulse rate such as 30 Hz to a rising-edge sensitive clock input of a D-type flip-flop 310. A
30 higher frequency pulse, some derivative of the same clock, e.g. 60 kHz to result in a 1:2000 duty cycle, furnishes a reset to the flip-flop 310 a brief period

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later. As a consequence, the flip-flop 310, which has its data input connected to a positive supply 314, clocks in a logic high which is reset 15 microseconds later by the higher frequency clock. The inverting output Q' of the flip-flop 310 is used and a corresponding 15 microsecond logical low pulse is subsequently generated. This low pulse appears at an inverting amplifier 317 which drives an output pin on the chip, and also appears at a rising-edge sensitive clock input of second flip-flop 320. The buffered output pulse from the inverter 317 passes to an external resistor 324.

The external resistor 324 performs a charge current limiting function in the external R/C circuit formed with the diaper's capacitor-switch network 327. The latter includes a first capacitor 330 formed by one of the members 127 and one of the pads 117 facing each other across the sheath 110, the resistance 334 of the switch formed by the electrodes 114 and the gap between them, and a second capacitor 337 formed by the other of the members 127 and the other of the pads 117 facing each other across the sheath 110.

The voltage at the resistor 324 and across the capacitor switch network 327 also appears at a Schmidt input buffer 340 which produces an output at the D input of the flip-flop 320. The flip-flop 320 is set at power-up to avoid a brief alarm. An output Q' of the flip-flop 320 drives an alarm 344. In the example shown in Fig. 3, the alarm 344 includes a beep-producing piezoelectric crystal PZ, an LED, a radio transmitter RT, an infra-red transmitter IR, a music generating circuit MG, and a tactilely-sensible

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vibrator VB for enuresis training, any of which may be energized selectively, either alone or all together. The piezoelectric crystal PZ may also produce ultrasonic chirps to communicate the alarm to a remote or bedside receiver. According to other embodiments of the invention, the sensor 124 includes any one or more of the crystal, LED, radio transmitter, infra-red transmitter, music generating circuit, or a tactilely-sensible vibrator without the others. The others may be omitted. Other means of alarm may be used. In one embodiment only the piezoelectric PZ and the LED is used.

In each charge cycle a 15 microsecond current-limited pulse feeds into the capacitor-switch network 327. Assuming the network 327 is initially discharged, it begins to acquire a charge, the terminal voltage of which is a function of the charging source voltage, current-limiting resistor 324, the pulse length, and the capacitance of the series-connected capacitors in the sensor network 327. When the diaper is dry the open circuit at the switch 324 between the electrodes 114 allows the charge across the circuit 327 to rise rapidly toward its peak and beyond the threshold of the Schmidt trigger 340. This places a low at the output Q' of the flip-flop 320. This holds the alarm 320 off. The voltage rises rapidly because, in the proximity of the dry layer 107, the total capacitance of circuit 327 is extremely low, much lower than the series capacitance of the capacitors 330 and 337.

When urine electrolytically shorts the electrodes 114, the total capacitance of network 327

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5 rises substantially to approximately the series
combination of the value of the far higher capacitance
of coupling capacitances 330 or 337. The Schmitt
network 327 then appears as a capacitive load equal to
approximately the value of the series combination of
the fixed coupling capacitances 330 and 337. The
voltage across the network 327 then fails to rise above
the positive-going threshold of the Schmidt trigger
340. At the termination of the sensing pulse from
10 flip-flop 310 and inverter 317, flip-flop 320 is
clocked by the rising Q' output of flip-flop 310 and
stores the logic low level output of Schmitt trigger
340 as a logic high level on its Q' output. This high
level on the Q' output of flip-flop 310 activates the
15 alarm 344. At the next pulse, when the flip-flop 310
resets the flip-flop 320, the output at Q' of the flip-
flop 320 goes high and triggers the alarm 344.

More specifically, the resistor 324 has a
value such that the network 327 charges to at least the
20 threshold (typically 1.6 volts) of a Schmidt input
buffer 340, when the diaper is dry. Thus, at the time
of charge termination, and the exact moment when the
synchronous rising-edge clock is fed to the second
flip-flop 320, the instantaneous level of the output of
25 the Schmidt input buffer 340, being a function of its
presently imposed input voltage, is clocked into the
sampling flip-flop 320. The resulting state of the
outputs of flip-flop 320 indicate the wet or dry state
of the diaper in that previous instant and the whole
30 cycle recurs at the previously mentioned 30 Hz rate.

When the diaper is dry, the flip-flop 320
produces a 0 at the Q' output. When the diaper is

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wet, the charge does not reach the level needed to cause the Schmidt input buffer 340 to apply a 1 to the D input of the flip-flop 320. This produces a 1 at the Q' output of the flip-flop 320 and activates the alarm 344.

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Beside the usual noise-reducing function typical of Schmidt input circuits, this Schmidt input buffer 340 provides an additional effect. As the network charging pulse voltage varies in response the power supply, so too varies the threshold voltage of the Schmidt input buffer 340. This is because the Schmidt threshold points are set by a voltage divider as a fixed, moderate fraction directly from the supply voltage. The effect is the reduction of supply voltage-induced variations in the sensing threshold as the battery voltage supply weakens, as would tend to be the case when batteries are used as the power source.

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The low pulse rate at the resistor 324 serves at least two purposes. First, a relatively long zero-voltage cycle helps assure that the voltage at the network 327 returns to zero between pulses under all conditions. Each cycle therefore tends to be isolated from the previous one. The low duty cycle assures the bias of the external capacitive network 327, thereby eliminating the need for resistive bias components were, for instance, a comparator used and were the applied waveform a 50% duty cycle square wave. Second, the average current required by the test circuit is reduced by making the tests less frequent than they might otherwise be, since the majority of test current is drawn during the pulse. Since the required response is in the order of one or more seconds, the average

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current consumption could theoretically be reduced to a minimum by reducing the duty cycle to the extent that the interval between pulses is made to be on the order of the required response time.

5 According to an embodiment, for a duty cycle of 1:2000 for the applied pulse, the values of the resistor 324 and the threshold of the Schmidt trigger can be selected so the average power applied to the series resistor, coupling capacitors, and electrodes
10 approximates 3 nanowatts of power.

 Figs. 4 and 5 illustrate an embodiment of a pouch. Here, an adhesive holds an outer curved flange 407 of an elastic pouch 410 against the outside of the outer water-impermeable electrically-insulating sheath 110. According to another embodiment of the invention,
15 a thermal bond holds the flange 407 to the sheath 110. When the sensor 124 is inserted into the pouch 410, the pouch shapes itself securely about the sensor.

 Fig. 6 is a plan view of the rear of an
20 embodiment of a diaper with a pouch 410 on the outside of the sheath 110 and containing a sensor 124. Fig. 7 is an frontal elevation of the rear of the diaper, when opened, in Fig. 6. Here, the thicknesses are exaggerated for clarity. The sensor 124 in the pouch
25 410 carries the members 127 and presses them against the outside of the sheath 110 opposite the pads 117 printed on the inside of the sheath. A substrate 600 supports the pads 117. A layer 604 common to existing disposable diapers covers the pads 117 and the sheath
30 110, and provides a mounting surface for an absorber layer 607 corresponding to the layer 107. The latter

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is also common to most disposable diapers. Covering the absorber layer 607 is a relatively hydrophobic inner sheet 610, also common to disposable diapers, and corresponding to the sheet 104. The relatively hydrophobic fibers space the wet mass of the layer 607 from the skin of the wearer and do not conduct moisture back to the skin. This keeps the skin dry even when the wearer has wet the diaper. The urine is held away from the skin by the competition between the highly absorbent layer 607 and the not-so-absorbent sheet 610.

Fig. 8 is a plan view of the rear of another diaper similar to the diaper in Figs. 6 and 7, but using bare wires or conductive threads 614 as the electrodes 114. Fig. 9 is an frontal elevation of the rear of the diaper, when opened, in Fig. 8. Here also, the thicknesses are exaggerated for clarity. The bare wires or conductive threads electrically connect to the pads 117 as they are squeezed between the pads and the sheath 110. According to another embodiment, the wires or conductive threads 614 pass through the absorber layer 607.

In the embodiments of Figs 6 to 9, as in other embodiments, when the diaper is dry the sensor 124 produces no alarm. The spaced electrodes 114 form the electrically conductive switch that remains open when the diaper is dry. Varying current from the source can then not pass through the open switch formed by the electrodes 114. When the diaper is wet, the electrolytic action of the urine in the diaper contacts the electrodes 114 and closes the switch, i.e. across the gap between the electrodes 114. The varying voltage of the source then passes a current from the

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sensor 124 through the capacitor formed by one member 127 and the opposing pad 117, through one electrode 114 through the electrolytically conductive gap between electrodes to the other electrode 114, through the capacitor formed by the second of the pair of pads 117 and the second of the pair of members 127, back to the sensor. The resulting current energizes the alarm which, according to one embodiment, energizes a piezoelectric sounder and plays a tune or makes some other sound such as a beep.

According to another embodiment of the invention, the sheets 104 and 610 are omitted to give the wearer a sensation of wetness and reinforce the alarm.

According to another embodiment, the wires or threads 614 are buried in the absorber layer 607 and fixedly contact a pair of thin plates within the layer 607. The sensor 124 with the members 127 is then insulated and also buried in the absorber layer.

According to another embodiment, the arrangement is the same as in Figs. 1 to 9, but rather than using pouches, the sensor 124 with members 127 is fastened to the sheath 110 by mechanical clips, snaps, or quarter turn locking units on the outside of the diaper.

Fig. 10 is perspective view of an embodiment of a sensor 1000 corresponding to the sensor 124. This includes a housing 1004, an extractor tab 1007, slightly-downwardly tapered sides 1010 and beveled edges 1014. The tapered sides permit alignment on insertion into a pouch. An optional spring loaded switch 1017 is turned on when the sensor 1000 is placed

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in a pouch. The dimensions of the sensor 1000 are such as to fit securely in a pouch. The housing has a rear face 1020 which is curved to furnish a contact force against the sheath 110 and the pouch when place in a

5 pouch.

According to other embodiments, the pads 117 use very thin layers of metals selected for reflectivity as well as oxidation and corrosion resistance. Sputtered or vaporized aluminum covered

10 with nickel avoids oxidation and presents an aesthetically pleasing white appearance outside the diaper.

According to other embodiments, the sensor arrangement is used to inflate a life vest when the

15 vest touches water, in bird feeder water supplies to indicate dry conditions, security doorknobs which respond to skin moisture, liquid level sensors, plant soil moisture indicators, etc.

The invention permits a mother to tend to a newborn infant or toddler, to alert a child during

20 toilet training that it is wetting, to help in enuresis training, and to forewarn the incontinent elderly of a problem before it arises. The invention avoids connecting the source mechanically to the conductors in

25 the diaper from the outside. It also frees the skin of the person wearing the arrangement from direct contact with the voltages that the source applies to the electrodes. Moreover, it avoids a false alarm when the

30 wearer sits on a wet or metal bench, leans on a wet or metal wall, or descends on a metal or wet park slide.

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According to other embodiments of the invention, the non-conductive coupling from the sensor to the electrodes is optical rather than capacitive. This involves using an LED and light detector combination on opposite sides of the sheath 110. According to another embodiment, the non-conductive coupling from the sensor to the electrodes is magnetic. This involves applying an electromagnetic field from the sensor in the pouch and then having the field sensed inside the diaper. According to another embodiment, the non-conductive coupling from the sensor to the electrodes is inductive from the sensor to the electrodes.

According to another embodiment of the invention, the speed of the response of the switch formed by the electrodes 114 is varied by changing the relative hydrophobic and hydrophilic correlations of the layers 104 and 107.

The sizes of the members 127 and the pads 117 are sufficiently large, and the face to face spacing between each pad 117 and the opposing member 127 across the dielectric sheath 110 is sufficiently small, so that the capacitances 330 and 337 formed thereby are substantially greater than the very small, almost unmeasurable, stray capacitance between the side-by-side electrodes 114. The Schmidt trigger 340 is set at a low enough value, and the capacitances 330 and 337 are sufficiently high, so that even when a child sits on a wet or metal surface, the stray capacitance across the switch 334 formed by the electrodes 114 does not add enough capacitance to the series circuit 327 to drop the input to the Schmidt trigger below its

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positive-going threshold. Hence, the flip-flop 320 will not set off a false alarm in response to the wearer sitting on a wet or metal surface. The dimensions are set to set off the alarm only in response to conduction across the switch 334 formed by the electrodes 114.

Fig. 11 is a block diagram of another embodiment of the invention wherein a processor 1400 performs the functions of the circuit 300 and members 340 and 320 in Fig. 3. The structure of the system is otherwise the same as shown in Fig. 3.

Fig. 12 illustrates the steps performed by the processor 1400. Here, in step 1504, the processor 1400 powers up in response to the detector module 20 being turned on, for example, when it is placed in the pouch of a diaper for the first time (i.e., by a latching switch activated by one of levers 37A or 37B).

In step 1507, the system is reset after a predetermined elapse of time. In step 1510, the processor 1400 detects the hard wire condition to determine which of the devices in alarm 344 are connected for the purpose of creating the alarm. In step 1514, the processor 1400 determines whether the system is set for an alarm to occur immediately upon sensing or whether a short delay should occur. In step 1514, the processor 1400 may also determine whether the number of operations (alarm conditions) should be counted, said counting to occur only after the aforementioned short delay has expired.

In step 1517, the processor 1400 generates

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pulses on a continuous basis. As shown in figure 3, these test pulses are applied to network 327 via resistor 324. In "threshold reached?" decision step 1520, the processor 1400 determines whether the voltage
5 has reached a predetermined value, typically a moderate fraction of the supply voltage, such as 40%.

If the result is YES, this means that a conductive condition is not present at switch 334, and the sequence of steps that could lead to activation of
10 the alarm is not begun. Instead, upon each such determination, in the "final alarm counted" decision step 1528, the processor checks whether the alarm counter had flagged a final alarm during the previous alarm event. If the alarm counter was not enabled in
15 configuration step 1514, then the result of this decision will always be NO. If it is YES, step 1530 disables the outputs so that the unit will no longer function. If NO, step 1532 initializes the delay timer (it does not matter whether or not the delay timer is
20 actually flagged for use in qualifying alarm conditions). Next, the "alarm in progress?" decision step 1535 checks whether there is an alarm condition present. If YES, step 1538 deactivates whatever signals had been active, and the processor returns to
25 the "threshold reached?" decision step 520. If NO, step 1538 is skipped, and the processor returns directly to the "threshold reached?" decision step 1520.

If the result of the "threshold reached?"
30 decision step 1520 is NO, this means that a conductive condition is present at switch 334, and the sequence of steps that could lead to activation of the alarm is begun. Upon each such determination, the "delay

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feature engaged?" decision step 1522 checks whether the delay feature has been flagged as being engaged. If YES, the "delay underway?" decision step 1524 checks whether a delay is currently underway. If YES, the unit will pulse the LED output pin at 8 Hz and return to the decision step 1524, where it will continue to check for the end of the delay period, rather than proceed with an alarm condition. If an LED is connected, a user of the product can see that a qualified alarm may be imminent, which helps prevent inadvertent activation of the alarm counter due to some form of mis-handling of the unit. Once the delay period is over, the result of the "delay underway?" decision step 1524 will become NO, as long as the result of the "threshold reached?" decision step 1520 persists in the NO condition, and this is what results in a positive alarm condition.

Fig. 13 is a continuation of the flow chart in Fig. 12, showing the steps that may occur upon the occurrence of a positive alarm condition. First, in step 1604, the alarm counter is incremented by a count of one, if it was enabled in the configuration step 1514. Next, in step 1521, the alarm condition is latched (i.e., by use of a persistent flag). Then, in the "last alarm?" decision step 1607, the processor checks whether this is the last alarm. If the alarm counter was not enabled, this decision will always be NO. If it is YES, the processor pulses the LED pin at 8 Hz, contrary to the usual 2 Hz rate, to indicate that the unit will not function after this alarm. Next, the "piezo?" decision step 1618 checks whether configuration step 1510 flagged that a piezo is connected. If YES, then the processor will feed the

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non-LED output pin with a signal that will cause an audio piezo transducer to produce a steady monotone. This tone is different from the usual warbling tone to indicate that the unit will not function after this alarm. If NO, then the processor will supply DC power the non-LED output pin for the purpose of driving any of a number of possible output devices.

If the result of the "last alarm?" decision step 1607 is NO, the processor pulses the LED pin at 2 Hz. that the unit will not function after this alarm. Next, the "piezo?" decision step 1619 checks whether configuration step 1510 flagged that a piezo is connected. If YES, then the processor will feed the non-LED output pin with a signal that will cause an audio piezo transducer to produce a warbling tone. If NO, then the processor will supply DC power the non-LED output pin for the purpose of driving any of a number of possible output devices.

It will be evident that certain details of the internal logic of processor 1400 are different from circuit 300, most obviously the latching of the alarm condition. This was done to facilitate implementation in software/firmware. The essential functions, however, remain common to the two.

With reference to the use of the alarm counter in any implementation, in the usual commercial context, it is expected that a detector module 20 has sufficient battery power to operate with one pack of diapers. Any attempt to use the device with a second pack of diapers would likely result in a failure of operation at some time during use with one of those

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diapers due to the dead or dying battery. Accordingly, the processor 1400 and the circuit 1700 count the number of operations and continue in operation only for the number of diapers in a single package. The number of possible alarms may be increased slightly over the package count to allow for the possibility of inadvertent alarms caused by mis-handling (such as re-insertion into an already wet diaper). This assures continued operation without failure in the middle of a pack.

Fig. 14 is a block diagram of a chip 1700 that, according to an embodiment of the invention, serves in place of the circuit 300, Schmitt trigger 340, and flip-flop 320 of Fig. 3, or in place of the circuit 300 of Fig. 3 or in place of the processor 1400 of Fig. 11. The chip 1700 senses the state of the switch 334 in the network 327. Specifically it senses whether a conductive condition is present at switch 334 in the network 327, indicating the presence of a conductive electrolyte across the sensing electrodes, as evidenced by the effect of the load presented by the series combination of substantially fixed-value capacitors 330 and 337 on the voltage at the connection to network 327 as of the end of the sensing pulse. The basic concept used is to generate short, current-limited, periodic, electrical test pulses to network 327. If network 327 is connected by the closure of switch 334, then network 327 serves to load down the test pulse, but if switch 334 is open, the pulse will be for practical purposes unaffected. The circuit checks the voltage at the connection to network 327 at the end of each pulse, and can detect the state of switch 334 by comparing this voltage to a predetermined

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threshold.

Fig. 15A illustrates the test pulse applied to the network 327, and Figs. 15B and 15C illustrate the waveforms induced on the network 327 by the test pulses after current limiting by an external resistor using typical values. There is a schematic insert indicating the nodes on an equivalent circuit for which the voltages are plotted. V(1), the test pulse, is shown in Fig. 15A. V(2), the voltage across network 327 for the case of a dry diaper, is shown in Fig. 15B. V(2) is also shown in Fig. 15C, this time for the case of a wet diaper. The sensing threshold is shown in Figs. 15B and 15C as a level at approximately 0.8V. The distortion seen in the waveform in Fig. 15B for the case of a dry diaper is caused by the deliberate inclusion of relatively large strays in the simulation model to demonstrate immunity to such strays.

Fig. 16 illustrates the pins of the chip 1700. It shows the external circuit connections to the CT chip. The connection (pin) characters shown in Fig. 16 correspond to those in Fig. 14.

The chip 1700 structure offers several different module configurations to satisfy the needs of different users. The primary module implementations appear in Figs. 17, 18, 19, 20, and 20A.

Fig. 17 illustrates the operation with a piezoelectric element as the only output. Here, the piezoelectric element PE is connected between the "B" and "C" pins and the "A" pin is left unconnected. The sensing circuitry is the same in all of the

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configuration illustrations. The supply voltage applied across the "+" and "-" pins is shown as a battery B. The "D" pin input is shown to be optionally connected to either the "+" pin or to the "-" pin. This provides two versions for each configuration; the delay and count operation may or may not be enabled in each of the five configurations of Figs. 17 to 20 and 20A.

Fig. 18 illustrates the operation with an LED as the only output. The LED is driven from the "B" pin. The "C" pin is connected to the "-" pin to prevent spurious piezoelectric element detection and the "A" pin is left unconnected.

Fig. 19 illustrates the operation with piezoelectric and LED outputs. Here, the LED is driven from the "A" pin and the piezoelectric element PE is driven from the "B" and "C" pins.

Fig. 20 illustrates the operation with an LED and external DC-powered output circuit. Here, the LED is driven from the "B" pin. In this configuration the "C" pin is connected to the "-" pin to prevent spurious piezoelectric element detection and the "A" pin is used to provide a constant DC voltage output to provide, or cause to be provided, a supply voltage for the external output circuit. According to an embodiment of the invention, the external output circuit is a device which plays a melody or sound effect, drives a motor or vibrator, activates a relay, generates a radio signal or infrared signal to a remote receiver, etc.

Fig. 20A illustrates operation with an external DC-powered output circuit only. Here, the "B"

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pin is left unconnected in this configuration and that as in the previous configuration, the "C" pin is connected to the "-" pin to prevent spurious piezoelectric element detection and output of the "A" pin furnishes a constant DC voltage output to provide, or cause to be provided, a supply voltage for the external output circuit. According to an embodiment of the invention, the external output circuit is a device which plays a melody or sound effect, drives a motor or vibrator, activates a relay, generates a radio signal or infrared signal to a remote receiver, etc.

A pin designated "+" is connected to the positive supply voltage. A pin designated "-" is connected to the negative supply voltage (or ground). According to an embodiment of the invention, the difference between the positive and negative supply voltage is greater than 2 volts and less than 6 volts (DC). Another embodiment provides for higher supply voltage differences and yet another embodiment provides for lower supply voltage differences.

In normal operating mode, an "R" pin provides the sensing pulses to the external network 327. In a Test1 mode, this pin provides access to the most significant output bit of a primary 15-bit counter to verify operation of the ripple count function. In a TEST2 mode, this pin provides a 32 kHz pulse train with approximately a 50% duty cycle.

In normal operating mode and in TEST2 mode, an "S" pin is the sense input from the external network 327. In TEST1 mode, this pin provides access to the oscillator tank circuit.

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In normal operating mode, a "D" pin is tied either to the pin "+" or the pin "-" prior to the application of power to the chip. If this pin is connected to the pin "-" when power is applied, all detected alarm conditions are indicated by signaling on the "A", "B", and/or "C" pins immediately following the end of each sense pulse and the operation counter function is inhibited. If this pin is connected to the pin "+" when power is applied, then a 4 second qualification timeout is observed prior to alarm signaling on the outputs. If the alarm condition does not persist throughout this qualification period, the pending alarm is canceled. If the alarm condition does persist throughout this period, alarm signaling appears at the outputs when the qualification period expires and the operation counter is incremented. If a falling edge is provided to this input while in normal operating mode, the chip enters the TEST1 mode, the primary 15-bit counter is set to all ones, and the clock input to the primary counter is disabled. A second falling edge arms the primary counter to be clocked by the next rising edge on this input. The next rising edge causes the primary counter to "roll-over" from all ones to all zeroes. The next falling edge causes a reset to be delivered to the circuitry. The fourth falling edge removes the reset and enables subsequent rising edges on this pin D to clock the primary counter directly. Additionally, the fourth falling edge causes exit of the TEST1 mode and entry of the TEST2 mode.

In normal operating mode, an "A" pin provides either a light emitting diode (LED) drive signal or a high level DC voltage (near supply voltage at the pin

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"+" dependent on loading) when an alarm condition is sensed. If there is no alarm condition, pin A is in a high-impedance state. In the TEST1 mode, this pin provides access to the output of the on-chip oscillator (64 kHz +/- 30%). In the TEST2 mode, pin A resumes its normal function.

In normal operating mode, a "B" pin immediately after the application of power, provides the piezo sensing pulse. After the piezo sensing function is completed, this pin provides either a piezo drive signal or an LED drive signal when an alarm condition is sensed. If there is no alarm condition, this pin is in a high-impedance state. Neither the TEST1 mode nor TEST2 mode has any direct effect on the function of pin B.

In normal operating mode, a "C" pin serves immediately after the application of power, to route the piezo element sensing signal to internal circuitry. After the piezo sensing function is completed, this pin provides a piezo drive signal when an alarm condition is sensed (only if the presence of a piezo element was sensed between the "C" pin and the "B" pin). If direct piezo drive is not to be used for a given circuit arrangement, this pin should be tied to the "-" pin which will assure that no piezo element is sensed. Making this connection will also guarantee that the "C" pin is permanently left in the high impedance state.

In Fig. 14, an analog section 1704 of the chip 1700 provides all the bias and reference voltages necessary for operation of the oscillator, power-on-reset circuit and the Schmitt trigger functions as well

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as those functions themselves. Shortly after power is applied between the "+" and "-" pins, the oscillator function starts and the POR (power-on-reset) and OSC signals are fed to a built-in test circuit block 1707.

5 Additionally, the analog section 1704 contains the Schmitt trigger circuit which is used to convert the analog signal present at the connection to the network 327 to discrete digital logic levels for sensing by the sensor signal detector. An OSC signal comes from the

10 micropower oscillator and has a nominal frequency of 64 kHz. A POR signal is a short pulse produced by a monostable multivibrator.

A "D" Pin Capture flip-flop 1710 is clocked by the POR signal shortly after power is applied and is

15 used to capture the power-up state of the "D" pin. The output of this block is a signal called DELON. If DELON is high following the POR pulse, then alarm qualification counter 1714 and operation counter 1717 are enabled for subsequent alarm detection processing

20 and the LED blink rate is switched to 8 Hz during the alarm qualification timeout period. If DELON is low following the POR pulse, then the alarm qualification counter 1714 and operation counter 1717 functions are inhibited for subsequent alarm detection processing and

25 the LED blink rate is always 2 Hz when an alarm condition is detected.

The built-in test circuit block 1707 controls a primary 15-bit counter 1720 with set, reset, and clock signal outputs based on activity on the "D" pin

30 subsequent to the end of the POR pulse. The TST1 output from this block 1707 controls the signaling on the "A" pin while in the TEST1 mode. It also controls the

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frequency and duty cycle of the signal output on the "R" pin. The TST2 signal is used strictly to control the test frequency multiplexer and, once asserted by the fourth falling edge on the "D" pin as described above, remains asserted until a full power off/on cycle is detected.

The primary 15-bit counter 1720 provides all of the key timing signals for chip operation. It is a 15-bit binary ripple counter which is normally clocked at the nominal oscillator frequency of 64 kHz. In the TEST1 mode, it can be manipulated by various transitions on the "D" pin (see "D" pin description above). In the TEST2 mode, it is clocked by the signal present on the "D" pin.

A test frequency multiplexer 1724 is a 9-wide 2-to-1 multiplexer. Eighteen inputs are fed by various outputs of the primary counter 1720. Nine outputs are timing signals used for sense signal generation and detection, LED blink rate, piezo detection, piezo tone generation, and alarm qualification counter timeouts. This block is controlled by the TST2 signal which is generally used to increase the various frequencies for manufacturing test purposes (to decrease test times).

A sensor signal generator 1727 receives timing from the primary counter 1720 via the test frequency multiplexer 1724 (32 Hz and 32 kHz) and an enable signal from a piezo presence sensor block 1730. When the piezo presence sensing function is completed, the piezo presence sensor block 1730 produces the GOSENSOR signal. This signal enables the signal generator 1727 to produce a sensing signal whose

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frequency is nominally 32 Hz (64,000 divided by 2^{10}) and whose duty cycle is 0.05%. The SENSE_OUT output of this block is the signal on the "R" pin. The SAMPLE output of this block is used to provide a synchronous sampling clock to a sensor signal detector 1734.

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The sensor signal detector 1734 is reset at power-up time. Once the sensing function is enabled (by assertion of the GOSENSOR signal), the connection to network 327 is fed to the Schmitt trigger in the analog section (to convert the analog voltage present there to a discrete digital level) and the converted digital level is sensed by this block when the SAMPLE signal is asserted by the sensor signal generator. The SAMPLE signal is asserted simultaneously with the end of the sensing pulse.

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The chip 1700 provides a non-alarm condition feature. If the signal present at the connection to the circuit 1727 was above the upper (supply-voltage-tracking) threshold of the Schmitt trigger circuit, then the ALARM output signal of this block is not asserted and the ALARM_RESET output signal is asserted. The ALARM_RESET signal inhibits the alarm qualification counter 1714 from counting which, in turn, prevents any clocking signals from reaching the operation counter 1717.

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The chip 1700 provides alarm condition with delay and count feature. If the signal present at the connection to the network 327 was below the upper (supply-voltage-tracking) threshold of the Schmitt trigger circuit, then the ALARM output signal of sensor signal detector block 1734 is asserted and the

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ALARM_RESET signal is not asserted. If the DELON signal is high ("D" pin high when power was applied), then the alarm qualification counter circuit 1714 is enabled to begin the qualification delay and the LED blinker circuit sets the LEDALARM signal high and generates an 8 Hz signal on LEDFLASH. When the qualification timeout has ended, the signals QUALIFIED and QUALMUX are asserted. The QUALIFIED signal is used to increment the operation counter 1717 and change the LEDFLASH signal from 8 Hz to 2 Hz (except for last operation). The QUALMUX signal is used to satisfy several logic equations relating to the usage of the outputs dependent largely on whether a piezo was detected between pins "B" and "C" following the application of power.

The chip provides an alarm condition without delay and count feature. If the signal present at the connection to the network 327 was below the upper (supply-voltage-tracking) threshold of the Schmitt trigger circuit, then the ALARM output signal of block 1734 is asserted and the ALARM_RESET signal is not asserted. If the DELON signal is low ("D" pin low when power applied) then the alarm qualification counter 1714 remains disabled and the LED blinker circuit sets the LEDALARM signal high and generates a 2 Hz signal on LEDFLASH. The QUALIFIED signal is never asserted so the operation counter never increments. The QUALMUX signal is used to satisfy several logic equations relating to the usage of the outputs dependent largely on whether a piezo was detected between pins "B" and "C" following the application of power.

The chip 1700 provides an end-of-alarm

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condition feature. As soon as the voltage present at the connection to the network 327 is found to have returned above the upper (supply-voltage-tracking) threshold of the Schmitt trigger circuit, then the ALARM output signal of the block 1734 is de-asserted and the ALARM_RESET signal is asserted. All alarm activity stops and the outputs return to a high impedance state.

An LED blinker circuit 1737 has several inputs. The ALARM signal activates the basic function. The DELON, QUALIFIED, and LASTOP signals control the output frequency of a LEDFLASH signal. The frequency and pulse-width control timing signals which define the shape of the LEDFLASH signal are provided from the primary counter via the test frequency multiplexer (ALL_TIMING). An LEDALARM signal is asserted (primary operand in logic equation to generate LEDFLASH) whenever an alarm condition exists and either: (a) the delay and count feature is enabled and the operation counter has not reached its terminal count, or, (b) the delay and count feature is disabled.

A piezo tone generator 1740 also has several inputs. The basic tone references (2 kHz, 4 kHz, and the 2 Hz warble control) are provided by the primary counter via the test frequency multiplexer. The actual signal (ALTONE) to be generated from these basic inputs is controlled by the LASTOP signal from the operation counter. The time during an alarm condition at which the ALTONE signal is allowed to drive the outputs is controlled by the QUALMUX output from the alarm qualification counter.

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The generator 1740 produces a warbling tone when an alarm condition occurs and either: (a) the delay and count feature is disabled, or, (b) the delay and count feature is enabled and the current operation cycle is not the last operation. Under either of these conditions, the ALTONE signal is a fairly symmetrical square wave which is modulated between 2 kHz and 4 kHz at 2 Hz.

The generator 1740 also produces a Last Tone signal when an alarm condition occurs and the delay and count feature is enabled and the operation counter has reached its terminal count. The ALTONE signal is a fairly symmetrical square wave at a constant frequency of 4 kHz.

The piezo presence sensor 1730 is enabled immediately after power is applied to the chip. The activation signal is provided by the primary counter via the test frequency multiplexer. When this signal is asserted, the PZSENSE output of this block produces a single high-going pulse which causes the "B" pin control circuits to transfer this pulse to the "B" pin itself. During this pulse interval, the "C" pin output is disabled. If a piezoelectric buzzer is connected between pins "B" and "C" at this time, the pulse is capacitively coupled from the "B" pin to the "C" pin since a piezoelectric buzzer is electrically equivalent to a small capacitor. The presence or absence of this pulse (PZOIN) is then sampled by the block 1730. If the piezo was present, then the PIEZO signal is asserted. Otherwise, the PIEZO signal is not asserted. In either case, when the sampling is completed the GOSENSOR signal is asserted which, in turn, enables the sensor

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signal generator to begin transmitting the SENSE_OUT pulses and generating the SAMPLE signal to the sensor signal detector. It should be noted that devices other than piezoelectric buzzers may be used to form a connection between the "B" and "C" pins as long as the impedance is suitably low, say, below 1 million ohms.

The alarm qualification counter 1714 provides the delay portion of the delay and count function. Its purpose is to impose a four second delay between the detection of an alarm condition and the generation of alarm-related output pin signals. This functional block is activated when an alarm condition exists and the DELON signal is asserted. When the timeout has expired and the operation counter has not yet reached terminal count, the QUALIFIED signal is asserted. This signal is used to increment the operation counter 1717 by one count (1 count = 1 operation) and to change the LEDFLASH output of the LED blinker circuit 1737. When this function is enabled LEDFLASH starts generating an 8 Hz signal as soon as an alarm condition is detected. Once the alarm qualification timeout expires, LEDFLASH changes its frequency from 4 Hz to 2 Hz as a result of the assertion of the QUALIFIED signal. The assertion of the QUALIFIED signal also causes the QUALMUX signal to be asserted. The QUALMUX signal is used to satisfy several logic equations relating to the usage of the outputs, dependent largely on whether a piezo was detected between pins "B" and "C" following the application of power.

The operation counter 1717 counts the total number of alarms which persist beyond the four-second qualification timeout period. The purpose of this

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counter is related to diaper wetness sensing inasmuch as the number of diapers in a package varies both from product to product as well as from manufacturer to manufacturer. Since for this application the product
5 utilizing the chip is invariably battery operated and since the battery size for these products is selected to provide optimum energy capacity for the size of the package of diapers with which the product is shipped, this functional block is used to inhibit the chip from
10 operating once the expected end of useful life of the battery energy source is approached. The actual battery life is difficult to predict since the power consumption of the chip and related circuitry fluctuates wildly (maybe more than 1000:1) between the
15 dormant (non-alarm) and active (alarm) states. Variability in the duration of the alarm condition adds further uncertainty to the prediction.

A block identified as "A" Pin Control Circuit 1744 determines the manner of signaling present on the
20 "A" pin during alarm conditions and while in the different test modes. The active output signal level is a high voltage level. In TEST1 Mode, the on-chip oscillator signal appears on the "A" pin.

In TEST2 Mode, the "A" pin produces signals
25 equivalent to the signals described below, except that the sensor signal generator duty cycle in this mode is about 50%.

When the "A" pin signals in the normal
operating mode, the "A" pin signaling has five
30 different formats which depend on: (a) whether or not the delay and count function is enabled or, (b) if the

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delay and count function is enabled (regardless of whether or not the current operation is the last operation) or, (c) whether or not a piezoelectric buzzer (or other suitable electrical connection) is detected by the piezo presence sensor.

10 If the delay and count function is enabled and a piezo was sensed and the operation counter has not yet reached terminal count, the "A" pin produces an 8 Hz signal with a 31.25 ms active pulse width during the first four seconds after the alarm condition is detected. Once the four second delay expires, the "A" pin signaling changes to a 2 Hz signal with a 31.25 ms active pulse width. The low (about 6%) duty cycle is used to reduce power consumption.

15 If the delay and count function is enabled and a piezo was sensed and the operation counter has reached terminal count, the "A" pin produces another signal, for example, an 8 Hz signal with a 31.25 ms active pulse width during the entire alarm condition.

20 If the delay and count function is enabled and a piezo was not sensed, the "A" pin produces a high impedance state during the first four seconds after the alarm condition is detected. Once the four second delay expires, the "A" pin produces another signal, for example, a high voltage level approximating the voltage on the "+" pin for light loads. If the delay and count function is not enabled and a piezo was sensed, the "A" pin produces another signal, for example, a 2 Hz signal with a 31.25 ms active pulse

25 width during the entire alarm condition. If the delay and count function is not enabled and a piezo was sensed, the "A" pin produces another signal, for

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example, a high voltage level approximating the voltage on the "+" pin for light loads.

5 A block 1747 identified as "B" Pin Control Circuits determines the manner of signaling present on the "B" pin during alarm conditions and while in the different test modes. The active output voltage level is a high level.

10 The B pin control circuits 1747 are involved in piezo presence sensing. The block 1747 causes the "B" pin, shortly after power is applied to the chip, to sense the presence or absence of a connection between the "B" pin and the "C" pin. This involves generation of a single pulse of approximately 32 ms within approximately the first 100 ms of chip operation.

15 In the TEST1 Mode, the block 1747 produces signals on the "B" pin largely equivalent to the signaling cases described below except the sensor signal generator duty cycle in this mode is about 50%. In the TEST2 Mode the block 1747 applies signals on the "B" pin largely equivalent to the signaling cases described below except that the sensor signal generator duty cycle in this mode is about 50%.

25 In the normal operating mode the block 1747 applies signals on the "B" pin with six different formats which depend on: (a) whether or not the delay and count function is enabled or, (b) if the delay and count function is enabled (regardless of whether or not the current operation is the last operation) or, (c) whether or not a piezoelectric buzzer (or other suitable electrical connection) is detected by the

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piezo presence sensor.

5 If the delay and count function is enabled
and a piezo was not sensed and the operation counter
has not yet reached terminal count, block 1747
constrains the "B" pin to produce an 8 Hz signal with a
31.25 ms active pulse width during the first four
seconds after the alarm condition is detected. Once the
four second delay expires, the block 1747 causes the
"B" pin signaling to change to another signal, for
10 example, a 2 Hz signal with a 31.25 ms active pulse
width. If the delay and count function is enabled and a
piezo was not sensed and the operation counter has
reached terminal count, the block 1747 causes the "B"
pin to produce another signal, for example, an 8 Hz
15 signal with a 31.25 ms active pulse width, during the
entire alarm condition. If the delay and count function
is not enabled and a piezo was not sensed, the block
1747 causes the "B" pin to produce another signal, for
example, a 2 Hz signal with a 31.25 ms active pulse
20 width, during the entire alarm condition.
If the delay and count function is enabled and a piezo
was sensed and the operation counter has not yet
reached terminal count, the block 1747 causes the "B"
pin to exhibit a high impedance state during the first
25 four seconds after the alarm condition is detected.
Once the four second delay expires, the block 1747
causes the "B" pin to produce a "warbling" signal which
switches back and forth from 2 kHz to 4 kHz at a 2 Hz
rate.

30 If the delay and count function is enabled
and a piezo was sensed and the operation counter is at
its terminal count, the block 1747 causes the "B" pin

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to produce a constant 4 kHz signal with an approximately square shape for the entire duration of the alarm condition. If the delay and count function is not enabled and a piezo was sensed, the block 1747
5 causes the "B" pin to produce a "warbling" signal which switches back and forth from 2 kHz to 4 kHz at a 2 Hz rate.

A block 1750 designated as "C" Pin Control Circuits determines the manner of signaling present on
10 the "C" pin during alarm conditions and while in the different test modes.

The block 1750 is involved in piezo presence sensing. As described, the block 1750 causes the "C" pin, shortly after power is applied to the chip, to
15 sense the presence or absence of a connection between the "B" pin and the "C" pin. During this interval, the "C" pin serves as an input. In an embodiment of the invention, to prevent a piezo from being sensed, this pin is grounded during this interval.

In TEST1 Mode, the block 1750 causes the "C" pin to produce signals largely equivalent to the
20 signaling cases described below except that the sensor signal generator duty cycle in this mode is about 50%.

In TEST2 Mode, the block 1750 causes the "C" pin to produce signals largely equivalent to the
25 signaling cases described below except that the sensor signal generator duty cycle in this mode is about 50%.

In the normal operating mode, the block 1750 causes the "C" pin to produce three different

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signalling formats that depend on: (a) whether or not the delay and count function is enabled or, (b) if the delay and count function is enabled (regardless of whether or not the current operation is the last operation) or, (c) whether or not a piezoelectric buzzer (or other suitable electrical connection) is detected by the piezo presence sensor.

If the delay and count function is enabled and a piezo was sensed and the operation counter has not yet reached terminal count, the block 1750 causes the "C" pin to exhibit a high impedance state during the first four seconds after the alarm condition is detected. Once the four second delay expires, the block 1750 causes the "C" pin to produce another signal, for example, a "warbling" signal which switches back and forth from 2 kHz to 4 kHz at a 2 Hz rate. If the delay and count function is enabled and a piezo is sensed and the operation counter is at its terminal count, the block 1750 causes the "C" pin to produce another signal, for example, a high impedance state for the first 4 seconds of the alarm condition followed by a constant 4 kHz signal with an approximately square shape, for the remainder of the alarm condition. If the delay and count function is not enabled and a piezo was sensed, the block 1750 causes the "C" pin to produce a "warbling" signal that switches back and forth from 2 kHz to 4 kHz at a 2 Hz rate.

Figs. 21A to 40 illustrate other embodiments of the invention. In the exploded perspective view of Fig. 21A, a disposable diaper 2100 includes an inner sheet 2104 of a water-permeable film, generally known and hereinafter referred to as cover stock 2104, that

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overlies a wetness absorber layer 2107 of highly liquid-absorbent padding or other highly absorbent material, generally known and hereinafter referred to as the core 2107. In one embodiment the core 2107 may include granules or filaments of water-retentive polymer, such as polyacrylic acid. An outer, electrically insulating plastic film that is impermeable to liquid water, generally known and hereinafter referred to as the backing sheet 2110, supports two conductive spaced-apart electrodes 2114, in the form of metallic or other electrically-conductive strips, with low surface area, hereinafter referred to as the sensing electrodes 2114, that extend along the center of the backing sheet 2110. The backing sheet 2110 also supports a tissue 2108 and a barrier 2109. According to embodiments of the invention, the sensing electrodes 2114 electrically contact the core 2107, or the tissue 2108, or the barrier 2109. According to an embodiment of the invention, the sensing electrodes 2114 pass longitudinally through the core 2107. According to another embodiment, sensing electrodes 2114 project along the interior surface of the backing sheet 2110 in contact with the core 2107. According to another embodiment, the sensing electrodes 2114 are in the form of conductive filaments, threads or wires.

The sensing electrodes are connected electrically to widened conductive areas 2117, hereinafter referred to as coupling electrodes 2117, that serve to couple signals between the sensing electrodes 2114 and a detector module that is to be placed against the outer surface of the backing sheet 2110. The detector module is provided with pickup

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electrodes each of which couples non-conductively, for example capacitively, to respective coupling electrodes 2117.

5 An optional tissue layer 2108 may be in contact with the core 2107, that serves to distribute wetness more quickly and uniformly about the core 2107, and that also serves to bring wetness from core 2107 into close contact with sensing electrodes 2114.

10 An optional wetness barrier layer 2109 may be interposed between a portion of the sensing electrodes 2114 and the core 2107 or the tissue 2108, that may serve to prevent wetness in the core 2107 from reaching a defined portion of the sensing electrodes 2114. If barrier layer 2109 is soluble in water, the effect will be a delay before wetness reaches the covered portion of the sensing electrodes 2114. If barrier layer 2109 is not soluble in water, the effect will be a requirement that the wetness in the core 2107 reaches beyond the covered portion of the sensing electrodes 2114 before the wetness may be detected.

25 Pocket slip 2112 is bonded to backing sheet 2110 along all but one of its edges to as to form the pocket 2111. The pocket 2111 is positioned so that when a detector module is placed therein, the pickup electrodes in the pocket 2111 are registered opposite the coupling electrodes 2117. The bonded area of pocket slip 2112 is identified with cross-hatching. If pocket slip 2112 is composed of material that is resilient, then insertion of an item that is slightly larger than the relaxed size of the pocket 2111 into the pocket 2111 will deform the unbonded portion of

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pocket slip 2112, which will tend to hold such an inserted item snugly in place and apply tension to the area of backing sheet 2110 located beneath the unbonded portion of pocket slip 2112. If pocket slip 2112 is
5 composed of an inelastic material, then the same tension and secure insertion may be obtained by a combination of deformation of the backing sheet 2110 and deformation of the inserted item itself. According to one embodiment, one pair of the coupling electrodes
10 2117 and one pocket 2111 is located near either the front or the rear waistband of the diaper 2100, and in another embodiment, a separate set of these aspects is located near both waistbands.

In the exploded perspective view of Fig. 21B,
15 a disposable diaper 2100 includes a sensor carrier layer 2119, onto which the sensing electrodes 2114 and coupling electrodes 2117 may be printed or otherwise pre-assembled prior to assembly onto backing sheet 2110.

20 Figs. 22A, 22B, 22C, and 22D show four possible arrangements of sensing and coupling electrodes 2114 and 2117. These represent repeated patterns that are to be parted at the separation line 2140. The separation line 2140 may correspond to the
25 place where the diapers 2100 made in the machine direction are separated from one another near the end of the production line, or where sets of electrodes 2114 and 2117 that are printed or otherwise pre-assembled onto a carrier layer are separated prior to
30 placement onto the backing sheet 2110, or the separation line 2140 may simply be conceptual, where electrodes 2114 and 2117 are assembled repeatedly onto

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a diaper that is made in the cross-direction.

In Fig. 22A, sensing electrodes 2114 are discontinuous, and there are two pair of coupling electrodes 2117 for each pair of sensing electrodes 2114. This provides a pair of coupling electrodes near each waistband. In Fig. 22B, sensing electrodes 2114 are also discontinuous, but there is one pair of coupling electrodes 2117 for each pair of sensing electrodes 2114. This provides a pair of coupling electrodes near only one waistband. In Fig. 22C, sensing electrodes 2114 are continuous, and there are two pair of coupling electrodes 2117 for each pair of sensing electrodes 2114. This provides a pair of coupling electrodes near each waistband. In Fig. 22D, sensing electrodes 2114 are also continuous, but there is one pair of coupling electrodes 2117 for each pair of sensing electrodes 2114. This provides a pair of coupling electrodes near only one waistband.

The sensing electrodes 2114 may be filaments, wires, yarn, ribbon, foil, fabric or film made from conductive material. The sensing electrodes 2114 may be filaments, yarn, ribbon, fabric or film that bears conductive filler material, that is coated with conductive material, or with surfaces subjected to a conversion process or suffused with a material that renders said surfaces conductive. The sensing electrodes 2114 may be in the form of yarn that includes continuous or discontinuous lengths of conductive filament or wire, that is wrapped with conductive filament or wire, that is infused with material that is conductive, or that is infused with material that bears conductive filler material. The

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sensing electrodes 2114 may be liquid or plastic material that is conductive or that bears conductive filler material, such as a thermoplastic, wax, paste, gel, latex, adhesive, or ink, that may be selectively applied onto a surface or into an absorbent matrix by methods such as printing, rolling, or extrusion.

Sensing electrodes 2114 may be formed by the selective conversion or suffusion of portions of a surface of a film, fabric or tissue material by a process that renders said portions conductive. Sensing electrodes 2114 may be formed by the selective removal of continuous conductive coating or converted outer layer from surface of a film material such as by abrasion or photolithography to render multiple isolated conductive areas (electrodes) from a continuous piece of coated film. Sensing electrodes 2114 may be formed by the selective removal of portions of an electrode film, fabric or tissue material such as by die-cutting to render multiple isolated conductive elements (electrodes) from a continuous element of coated film, fabric or tissue material.

Sensing electrodes 2114 may be redundant, in that each of the two electrodes that make up a pair may have more than one strand, ribbon, strip, etc., and that these redundant elements may be of different morphologies.

The coupling electrodes 2117 may be ribbon, foil, fabric, tissue or film made from conductive material. The coupling electrodes 2117 may be ribbon, fabric, tissue or film that bears conductive filler material, that is coated or infused with conductive

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material, or with surfaces subjected to a conversion process or suffused with a material that renders said surfaces conductive. The coupling electrodes 2117 may be ribbon, fabric, tissue or film material that is
5 conductive or has one or both surfaces made conductive, where said structure is optically transparent or translucent. The coupling electrodes 2117 may be liquid or plastic material that is conductive or that bears conductive filler material, such as a
10 thermoplastic, wax, paste, gel, latex, adhesive, or ink, that may be selectively applied onto a surface or into an absorbent matrix by methods such as printing, rolling, or extrusion.

The coupling electrodes 2117 may be formed by
15 the selective conversion or suffusion of portions of a surface of a film, fabric or tissue material by a process that renders said portions conductive. The coupling electrodes 2117 may be formed by the selective coating of portions of a surface of a film, fabric or
20 tissue material with conductive material, such as by sputtering or thermal vapor deposition. The coupling electrodes 2117 may be formed by the selective removal of continuous conductive coating or converted outer layer from surface of a film material to render
25 multiple electrodes from a continuous piece of coated film. The coupling electrodes 2117 may be formed by the selective removal of portions of an electrode film, fabric or tissue material such as by die-cutting to render multiple electrode elements from a continuous
30 element of coated film.

Figs. 23A and 23B depict two embodiments of an electrode arrangement where a plurality of

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individual electrodes 2314 and 2317 may function together to effectively form pairs of electrodes corresponding to sensing electrodes 2114 and coupling electrodes 2117 in Figs. 21A and 21B and 22A to 22D.

5 In Fig. 23A, the electrodes are of uniform width, where the portions of these electrodes that are to function as the coupling electrodes 2317 are the portions that are located in coupling area 2316. In Fig. 23B, the sensing electrodes 2314 are narrower than coupling electrodes 2317. The arrangement of the electrodes into a plurality of parallel elements serves to provide great immunity to translational variation in the registration between the pocket 2111 and the coupling electrodes 2317.

15 Figs. 24, 25, and 26 depict three possible construction schemes pertaining to the placement of the electrodes relative to the other layers in the diaper 2100. Each figure is an elevation that cuts across a single coupling electrode 2117 in a direction
20 orthogonal to the sensing electrode 2114, and that includes all layers but the pocket 2111. These are simplified to the extent that certain adhesive applications and other typical or possible processes are not depicted, and no indication is given as to the
25 treatment of the various layers as they exist beyond the boundaries of the drawn area.

In Fig. 24, the backing sheet 2110 has been sprayed with the construction adhesive 2133, has had the sensing electrode 2114 laid down into the
30 construction adhesive 2133, has had the coupling electrode 2117, which is oriented so that the conductive coating 2118 is facing the sensing electrode

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2114, nipped down against the sensing electrode 2114, has had the tissue 2108 nipped down over both electrodes 2114 and 2117, has had the core 2107 nipped down over the tissue 2108, and finally had the cover 2107 nipped down over the core 2107.

An electrically conductive liquid, paste, putty, or powdered solid material may be deposited in the gap 2130 in contact with the sensing electrode and the coupling electrode.

Fig. 25 differs from Fig. 24 only in that barrier layer 2119 is added between tissue 2108 and sensing and coupling electrodes 2114 and 2117.

In Fig. 26, the side of the sensing electrode 2114 that bears the adhesive 2135 has been nipped down to the backing sheet 2110, and the side with the conductive coating 2118 faces outward. The tissue 2108 has been sprayed with the construction adhesive 2133, and the sensing electrode 2114 has been laid down into the construction adhesive 2133 in the tissue 2108, whereupon the tissue 2108 bearing the sensing electrodes 2114 has been nipped down to the backing sheet 2100 that bears the coupling electrodes 2117. This places the conductive coating 2118 on the coupling electrodes 2117 in contact with sensing electrodes 2114. The core 2107 is nipped down onto the existing structure, and ultimately the cover 2104 is nipped down over this.

An electrically conductive liquid, paste, putty, or powdered solid material may be deposited in the gap 2130 in contact with the sensing electrode and

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the coupling electrode.

Figs. 27 and 28 depict two possible arrangements of sensing and coupling electrodes 2114 and 2117 where they are incorporated into the core 2104. In both cases, sensing and coupling electrodes 2114 and 2117 are printed or otherwise pre-assembled onto a carrier layer 2119, and placed within the core 2104, with the ends bearing coupling electrodes 2117 protruding from its ends. In Fig. 27, the coupling electrodes 2117 are to be assembled to the backing sheet 2110 in an area near the waistband that is clear of the core 2104. In Fig. 28, the portion of carrier 2119 that bears the coupling electrodes 2117 is folded back over the core and is therefor located beneath the core in the finished diaper 2100.

In another embodiment, unsupported sensing electrodes 2114 are laid into the core 2107, and the coupling electrodes are brought down over them as in Fig. 24.

Fig. 29 is a detail of the pocket 2111 bonded to the backing sheet 2110, showing the bonded area around all but one edge of the pocket slip 2112.

Fig. 30 is the same as Fig. 29, except that one method of reinforcement of the unbonded edge of pocket 2111 is illustrated, where the edge that is not to be bonded to the backing sheet 2110 is folded over on itself one or more times and bonded to itself prior to or concurrent with the bonding of the pocket 2111 to the backing sheet 2110. In another embodiment, the open edge of the pocket 2111 is reinforced by bonding a

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separate strip of material to it.

Fig. 31 depicts the folding of the carrier strip 2119 bearing electrodes 2114 and 2117 so as to shorten its length. The Z-fold can be placed into the material as it is being assembled onto the diaper 2100, or prior to assembly.

Fig. 32 depicts an apparatus for abrading the conductive coating 2118 from the carrier strip 2119. Here, the rubber wheel 2210 rotates so that it rubs the carrier strip 2119 counter to its direction of travel.

Fig. 33 depicts an apparatus for applying the sensing electrodes 2114 into the construction adhesive 2133 on the backing sheet 2110. Reels of wire 3305 are fitted with appropriate feed, braking and anti-run-on means. Sensing electrodes 2114 in the form of wires take one or more turns around tensioning drums 3310, thread through direction control pins 3315, and are drawn onto backing sheet web 2110 by the motion of said web. Also depicted for clarity are pockets 2111, and frontal tape 2102. The backing sheet passes over a drum 3320.

Fig. 34 depicts an apparatus for removing the non-conductive fibers from the core of a yarn 3414 that has been spun-wrapped with wire to form an electrode 2114. Gaseous fuel source 3405 feeds gas to burner 3415. Gas flow modulator 3410 is connected in parallel with gas source 3405. Ignition source 3420 may ignite flame 3417. The yarn 3414 is drawn through the space directly over the flame, and the flame is modulated so

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that it vaporizes, melts, or partially vaporizes and partially melts the non-conductive fibers in the core of the yarn. The resultant segments of bare wire can make improved contact with conductive surfaces, such as coupling electrodes 2117.

Fig. 35 illustrates an example of a module 3504 having pickup electrodes 3507 in the pocket 2111 formed by the pocket slip 2112 on the backing sheet 2110. The pickup electrodes 3507 are positioned opposite, and are here non-conductively and capacitively coupled to, the coupling electrodes 2117 across the backing sheet 2110. Thicknesses are exaggerated for clarity.

Figs. 36 and 37 depict a portion of an embodiment of the backing sheet 2110 in the form a typical two-component cloth-like sheet 2110, composed of a non-woven fabric layer 2110A and a film layer 2110B, and containing a rectangular treated portion 3613. The treated portion 3613 includes a monolithic matrix of the non-woven fabric layer 2110A and the film layer 2110B. The treatment serves to increase the dielectric constant and decrease the thickness of the treated portion 3613, and to render it more amenable to later bonding of the pocket material. The treatment of the portion 3613 may be accomplished thermally or ultrasonically, but the preferred method is ultrasonic.

In Fig. 36, the treated portion 3613 is located centrally and near the front of the waistband, as indicated by the presence of the frontal tape 2102. According to other embodiments the treated area is alternatively or additionally located near the rear

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waistband or on another part of the diaper. For a given diaper construction, the position of the treated portion 3613 will tend to coincide with that of the pocket 2111 that is shown in various other figures.

5 Fig. 37 show the fibers of the backing sheet non-woven layer 2110A separate from and randomly oriented over the backing sheet film layer 2110B, except in the treated portion 3613. There, the two materials are shown combined into a monolithic matrix.

10 In addition to backing sheet film 2110B, the embedding encapsulant, according to embodiments of the invention, includes another material added to either side of the portion 3613 prior to treatment. This additional material may be a thermoplastic film that is
15 compatible with the backing sheet film 2110B, or it may be some other material that could serve the purpose of increasing the fraction of solid thermoplastic available to encapsulate the fibers of the non-woven backing sheet layer 2110A.

20 Fig. 38 depicts the basics of an ultrasonic apparatus for performing the treatment of the portion 3613. The backing sheet 2110 is conveyed continuously on the roll 3855 with the non-woven layer 2110B typically facing the ultrasonic horn 3850. The
25 ultrasonic horn 3850 is powered periodically, so that it supplies energy across its width to the backing sheet 2110 for uniform time periods at uniform time intervals. This is done to assure that uniform lengths of a narrow portion of the overall width of the backing
30 sheet 2110 are subjected to treatment at uniform spatial intervals. According to an embodiment of the

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invention, a rotary horn is used as an alternative to a stationary horn in order to eliminate the risk of the backing sheet 2110 becoming snagged on the horn.

5 In each of the embodiments of Figs. 21A to 38, the diapers are made by forming each of the components of the figures, for example the components 2104, 2107, 2110, 2111, 2112, 2114, and 2117, assembling the components with suitable adhesives or other adhering means to achieve the arrangements shown, 10 and then shaping them to the typical diaper shape. The order in which the components are formed or assembled may vary with the needs of the manufacturer.

A general manufacturing process may involve forming a liquid-impermeable backing sheet having an 15 exterior surface and an interior surface so as to produce an exterior of the diaper and an interior of the diaper, forming a liquid-absorbing arrangement and placing the liquid-absorbing arrangement next to the backing sheet, forming an elastic pocket and bonding 20 the pocket to the exterior surface of the backing sheet to contain a detector module, forming sensing electrodes and placing sensing electrodes within the interior of the diaper and within the interior surface of the backing sheet in contact with the liquid 25 absorbing arrangement in a direction to extend opposite the elastic pocket so as to allow the sensing electrodes to couple capacitively to the detector module, assembling the various components by bonding, and forming the product into the shape of a diaper. 30 The bonding of any component may occur at any phase of the process.

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Each of the elements formed and assembled are constructed to achieve the structure described for each of the figures and as described below. The process is finished by configuring the assembly into a diaper shape and adding elastics at the waist and legs and fastening strips 2130 to produce the diaper of Fig. 39.

According to embodiments of the invention, diapers are manufactured by automatic machine where component materials are supplied from rolls or other sources located at points in the line. In one example, the backing sheet runs as a web through the full length of the manufacturing line up to the point where the individual diapers are separated from one another. However, the backing sheet may be put in sheets. The other components are affixed continuously, individually, or in partially pre-assembled combinations upon the backing sheet 2110. In an exemplary machine direction assembly operation, at a point where the backing sheet web is fed in, the frontal tape is cut and placed onto the outer side of the backing sheet 2110, and the pocket 2111 is cut and bonded in place onto the outer side of the backing sheet 2110. Adhesive is applied onto the area where the coupling electrodes 2117 are to be placed, the sensing electrodes 2114 are fed in, the coupling electrodes 2117 are cut and placed, construction adhesive is applied to the entire surface, leg and waistband elastics are applied, and an absorbent pad 2107 that was formed off line is carried between a web of tissue layer 2109 and cover stock 2104 and fed in and affixed, and the backing sheet 2110 is cut to shape so as to narrow the crotch. Finally, the individual diapers are cut apart, separated, folded, and bagged.

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The order of these steps may change as desired..

An example of an automatic machine appears in Fig. 40. Here, a manufacturing line 4101 receives a web of material that forms the backing sheet, either pre-formed or uncut, from a backing sheet web source 4104. The line 4101 either moves the pre-formed backing sheets along the line or cuts the web to form the backing sheets. A liquid-absorber layer source 4107 supplies the components of the liquid-absorber layer, either individually or as a unit, either pre-formed or as linear sheets, to the line 4101. The line 4101 bonds the liquid-absorbing arrangement to the backing sheet made from the web. An elastic pocket source 4110 supplies an elastic pocket, pre-formed or uncut, to the line 4101 and the latter bonds the elastic pocket to the backing sheet made from the web. A sensing electrode source 4114 supplies sensing electrodes, in partially or completely shaped condition, to the line 4101 and the latter bonds them in the proper position in contact with the liquid-absorbing arrangement and opposite the pocket. An elastic source 4117 furnishes elastic to the line 4101, and the latter adds the elastic, and cuts and shapes the diapers into the state shown in Fig. 39. The line 4101 also separates, folds, and bags the diapers. According to various embodiments of the invention, each of the sources 4104, 4107, 4110, 4114, and 4117 assume different positions so that the order of processing may vary. The bonding may occur at phases of the process other than those shown. Also any one of the sources 4104, 4107, 4110, 4114, and 4117 may supply pre-formed or partially formed materials, and the line 4101 uses these material. Where the sources furnish incomplete

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or partially formed components, the line 4101 constructs the material into final forms.

5 According to embodiments of the invention, the sensing electrodes are made as any one or more of the following:

filament, wire, yarn, ribbon, foil, fabric or film made from conductive material

10 filament, yarn, ribbon, fabric or film that bears conductive filler material, that is coated with conductive material, or with surfaces subjected to a conversion process or suffused with a material that renders said surfaces conductive

15 yarn that includes continuous or discontinuous lengths of conductive filament or wire, that is wrapped with conductive filament or wire, that is infused with material that is conductive, or that is infused with material that bears conductive filler material

20 liquid or plastic material that is conductive or that bears conductive filler material, such as a thermoplastic, wax, paste, gel, latex, adhesive, or ink, that may be selectively applied onto a surface or into an absorbent matrix by methods such as printing, rolling, or extrusion

25 selective conversion or suffusion of portions of a surface of a film, fabric or tissue material by a process that renders said portions conductive
selective removal of continuous conductive coating
30 or converted outer layer from surface of a film material such as by abrasion or photolithography to render multiple isolated conductive areas (electrodes) from a continuous piece of coated film
selective removal of portions of an electrode film,

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5 fabric or tissue material such as by die-cutting to
render multiple isolated conductive elements
(electrodes) from a continuous element of coated
film, fabric or tissue material
electrodes may be in the form of a plurality of
stripes
each electrode may consist of a plurality of
conductors.

10 According to embodiments of the invention, the
attachment of the electrodes involves doing any one
or more of the following:
selective coating or application of conductive
material onto portions of a surface of a film,
fabric or tissue material where said surface may
15 be the backing sheet or where said film, fabric or
tissue material may be subsequently applied onto
said backing sheet
incorporation into pad, tissue, or other component
layer such as by weaving or laminating.

20 According to embodiments of the invention, the coupling
electrodes are made as any one or more of the
following:
ribbon, foil, fabric, tissue or film made from
25 conductive material
ribbon, fabric, tissue or film that bears conductive
filler material, that is coated or infused with
conductive material, or with surfaces subjected to
a conversion process or suffused with a material
30 that renders said surfaces conductive
ribbon, fabric, tissue or film material that is
conductive or has one or both surfaces made
conductive, where said structure is optically

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transparent or translucent
liquid or plastic material that is conductive or
that bears conductive filler material, such as a
thermoplastic, wax, paste, gel, latex, adhesive, or
5 ink, that may be selectively applied onto a surface
or into an absorbent matrix by methods such as
printing, rolling, or extrusion
selective conversion or suffusion of portions of a
surface of a film, fabric or tissue material by a
10 process that renders said portions conductive
selective coating of portions of a surface of a
film, fabric or tissue material with conductive
material, such as by sputtering or thermal vapor
deposition
15 selective removal of continuous conductive coating
or converted outer layer from surface of a film
material to render multiple electrodes from a
continuous piece of coated film
selective removal of portions of an electrode film,
20 fabric or tissue material such as by die-cutting to
render multiple electrode elements from a
continuous element of coated film
electrodes may be in the form of a plurality of
stripes.
25 According to an embodiment of the invention, connection
of each coupling electrode to each sensing electrode
are made as one or more of the following:
connection formed by conductive adhesive that is
printed, transferred, thermally bonded or otherwise
30 applied to the coupling electrode, the sensing
electrode, or to another surface to which the
electrodes are to be bonded
connection formed by physical contact, where sensing

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electrode is interposed between a coupling electrode and another surface, where a non-conductive adhesive is applied to said other surface that holds said coupling electrode to said other surface

connection optionally enhanced by presence of an electrically conductive liquid, paste, putty, or powdered solid material in contact with the sensing electrode and the coupling electrode

10 According to an embodiment of the invention, combined sensing and coupling electrodes are made as one or more of the following:

15 electrode pattern deposited or pre-assembled onto a carrier film, fabric or tissue, where pattern may be repeated continuously on a roll of material, either in the machine or cross directions, and where pattern may consist of pairs of sensing electrodes with coupling electrodes at one or both ends

20 when printed, the ink used for the sensing electrodes and the coupling electrodes may have different conductivity's electrodes that are uniform in width along their entire length

25 where diminished sensitivity to conditions external to the diaper may be attained by the placement of the electrodes so that one or more layers of dielectric material are interposed between the portion that will perform the sensing function and the backsheet

30 where the electrodes may be in the form of a plurality of stripes

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According to an embodiment of the invention, the pocket involves making it in one or more of the following ways:

- 5 composed of an elastomeric or plastomeric, solid or foamed, film or fabric material to retain a substantially non-deformable item, or a substantially inelastic film or fabric material to retain a spring-loaded deformable item
- transparent or opaque
- 10 printing with or without superficial or sub-surface
- formed by bonding a relatively small patch of material along all but one of its edges
- 15 directly to the backsheet to the bondable surface of a secondary patch of material, such as a label or frontal tape, that is applied to the backsheet
- reinforcement of the open edge by rolling and self-bonding an edge of the patch of material that will become the open edge prior to bonding onto a diaper or secondary patch of material
- 20 reinforcement of the open edge by bonding a strip of reinforcing material to an edge of the patch of material that will become the open edge prior to bonding onto a diaper backsheet or secondary patch of material
- 25 printing on transparent material, forming a portion of a graphic that is completed or changed when the pocket is occupied by an object bearing a corresponding graphic
- 30 acts to obscure a view of the electrodes from the exterior of a diaper

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According to embodiments of the invention, the attachment of the pocket to the backsheet involves any one or more of the following steps:

- 5 direct thermal or ultrasonic bonding;
- thermoplastic or thermosetting adhesive bonding
- adhesive as coextruded skin on pocket material,
- selectively bonded,
- adhesive selectively printed on pocket
- 10 material; allows selective bonding by heating
- full area,
- adhesive film co-laminated with pocket,
- selectively bonded
- adhesive printed or sprayed onto pocket
- material and selectively bonded;
- 15 bond directly to backsheet
- backsheet may be printed
- forming a portion of a graphic that is
- completed or changed when the pocket is
- occupied by an object bearing a
- 20 corresponding graphic,
- acting to obscure a view of the electrodes
- from the exterior of a diaper;
- bond to a label that is applied to the backsheet
- label may be variously opaque to obscure view
- 25 of electrodes,
- variously opaque material,
- variously opaque coating on transparent or
- variously opaque material,
- label may be printed
- 30 forming a portion of a graphic that is
- completed or changed when the pocket is
- occupied by an object bearing a
- corresponding graphic,
- acting to obscure a view of the electrodes

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from the exterior of a diaper;
 deformable module with a generally non-deformable
 pocket to achieve retention and tension;
 side levers on module
 5 actuate one or more switches,
 retain one or more batteries,
 provide tensile force against sides of pocket.

According to embodiments of the invention, the control
 mechanisms operate any one or more of the following
 ways:

10 interposition of a layer of water barrier film
 between the sensing electrodes and the absorbent
 material in the vicinity of the urine discharge
 area to prevent wetness from reaching said
 15 electrodes until the core is to some degree
 saturated;

interposition of a layer of water-soluble, water
 barrier film between the sensing electrodes and the
 absorbent material to impart a time delay prior to
 20 when wetness reaches the sensing electrodes;
 alteration of the length or the spacing or both the
 length and spacing of the sensing electrodes to
 alter the degree to which the core must be
 saturated and the speed with which wetness reaches
 25 said electrodes.

According to embodiments of the invention, the
 structures and orientations involve assembling the
 components to achieve any one or more of the following
 sequences:

30 backsheet/construction adhesive/sensing electrode/

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film coupling electrode/core
 backsheet/PSA/sensing electrode/ film coupling
 electrode/core
 backsheet/construction adhesive/sensing electrode/
 5 film coupling electrode/tissue/core
 backsheet/PSA/sensing electrode/ film coupling
 electrode/tissue/core
 backsheet/PSA/film coupling electrode/sensing
 electrode/construction adhesive/tissue
 10 backsheet/printed coupling electrode/sensing
 electrode/construction adhesive/tissue

According to embodiments of the invention, the methods
 for manufacture involve any one or more of the
 following steps:

15 adjustment of the length of combined sensing and
 coupling electrodes to match various diaper
 lengths, where said combined electrodes are first
 deposited or pre-assembled onto a carrier film,
 fabric or tissue with coupling electrodes at both
 20 ends, said length adjustment executed by imparting
 a double fold, generally known as a Z-fold, across
 the carrier film, such as during or proximal to the
 process of cutting and placing the combined
 electrodes onto a diaper backsheet
 25 clear a swath in the conductive coating on the
 coupling electrode material to render multiple
 electrodes from a continuous piece of coated film
 using abrasion
 rotating frictive wheel, such as of rubber
 30 rotating abrasive wheel, such as of grit-coated
 aluminum
 rotating wire or fiber wheel, such as of brass
 or polyester
 one or more blade edges, oriented so as to

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scrape rather than slice the material surface
using an electrical arc
using a beam of light, such as from a laser
incorporate coupling electrodes into a diaper by
5 unwinding electrode material from a roll or spool
where coupling electrode material is slit, cut and
placed
where electrode material may bear a coating of
conductive adhesive.
10 where another layer to which the coupling
electrode is being applied may bear a coating of
adhesive
where the adhesive may be pressure-sensitive or
thermally activated, transparent or variously
15 opaque
incorporate coupling electrodes into a diaper by
printing conductive ink onto backsheet
incorporate sensing electrodes into a diaper by
unwinding electrode material continuously in-line
20 with the backsheet in the case of diapers that are
made in the machine direction
where the electrode material is affixed to the
backing sheet
by laying it onto open construction adhesive
25 previously applied to the backsheet
by laying it onto the backsheet and keeping it
in tension before the construction adhesive is
applied
where the sensing electrodes are severed between
30 diapers
by the same blade or blades that separate the
diapers from one another
by an electric current applied to a relatively
short span of the sensing electrodes by knife

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edges in the region of the waistband
incorporate sensing electrodes into a diaper by
cutting and placing lengths of electrode material
where the electrode material is affixed to the
5 backing sheet
by laying it onto open construction adhesive
previously applied to the backsheet
by laying it onto the backsheet and keeping it
in tension before the construction adhesive is
10 applied
where the lengths of electrode material are cut to
length using one or more blades, water jets,
flames, or beams of light, such as from a laser
remove the non-conductive fibers from segments of a
15 continuous yarn containing or wrapped with one or
more conductive fibers or wires
by application of a flame
where the flame height and intensity is
modulated
20 by direct modulation of the gas flow
where the flow rate modulation is effected
by control of a valving orifice plumbed
in series with the gas flow
where the flow rate modulation is effected
25 by the motion of a piston in a cylinder
or a diaphragm in a cavity that has a
single inlet plumbed in parallel with the
gas flow
by modulation of the flow velocity of a
30 cross-flowing jet of air
by modulation of the flow into a cross-
oriented vacuum inlet
by a combination of the above
where the flame is interrupted periodically by

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a perforated solid or mesh disk, while optionally the gas flow is simultaneously modulated

5 where the flame is intermittently applied by moving the gas nozzle, while optionally the gas flow is simultaneously modulated by application of a jet of hot air (with similar approaches to modulation or interruption) by application of a modulated beam of light, such as from a laser

10 by application of a jet of water where the jet is intermittently applied by moving the nozzle, while optionally modulating the flow simultaneously.

15 According to embodiments of the invention, the coating materials involve incorporating one or more of the following:

metals for optically dense, electrically conductive coating, such as Ni, NiCr, Ni over Al, Sn

20 semiconductive oxides to create an optically transparent, electrically conductive coating, such as ITO, ATO, ZnO

multiple layers incorporating both metals and oxides to create an optically transparent, electrically

25 conductive coating, such as $\text{Al}_2\text{O}_3/\text{Ag}/\text{ITO}$

According to embodiments of the invention, the electrode materials are made as, or in any one or more of the following ways:

30 fabric made electrically conductive by impregnation with one or more salts that remain wet, and therefore ionic and conductive, due to the hygroscopic nature of the mixture, such as of

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calcium chloride and sodium chloride, or lithium
chloride and sodium chloride
electrically conductive putty composed of a mixture
of an electrically conductive filler and an oil
5 base, optionally made stickier by the addition of
one or more tackifiers, such as rosin.

According to other embodiments of the invention, the
other aspects of the structure or method involve one
or more of the following means or steps:
10 coat surface of item to be placed into pocket with
slippery coating, such as wax
coat interior surfaces of pocket with slippery
material, such as silicone oil.

While embodiments of the invention have been
15 described in detail it will be evident to those skilled
in the art that the invention may be embodied otherwise
without departing from its spirit and scope.

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What is claimed is:

1. A wetness detector for a detecting electrolytic wetness in a first area, said first area being subject to wetness, comprising:

5 a first electrode projecting into the first area;

a second electrode spaced from the first electrode and projecting into the first area;

10 a sensing device in the second area protected from wetness in said first area and non-conductively coupled to each of said electrodes and responsive to the impedance between said electrodes in said first area so as to produce a signal when the first area becomes wet and electrolytic wetness couples the electrodes in the first area.

15 2. A wetness detector as in claim 1, wherein said sensing device is capacitively coupled to said first and second electrodes.

20 3. A wetness detector as in claim 1, wherein said sensing device includes a first conductor in said second area protected from the wetness of said first area and capacitively coupled to said first conductor and a second conductor in said second area protected from wetness of said first area and capacitively coupled to said second conductor.

25 4. A wetness detector as in claim 1,

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wherein said sensing device includes a source of varying voltage coupled non-conductively to said first and second electrodes and a signal output responsive to reduction of impedance between said electrodes.

5 5. A wetness detector as in claim 2, wherein said sensing device includes a source of varying voltage coupled capacitively to said first and second electrodes and a signal output.

10 6. A wetness detector as in claim 3, wherein said sensing device includes source of varying voltage connected to said first conductor and to said second conductor, and further includes a signal output responsive to reduction of resistance between said electrodes.

15 7. A wetness detector as in claim 1, wherein said sensor includes a signal output responsive to reduction of resistance between said electrodes.

8. A wetness detector as in claim 7, wherein said signal output is audible.

20 9. A wetness detector as in claim 7, wherein said signal output is visible.

10. A wetness detector as in claim 7, wherein said signal output is in the form of radio waves.

25 11. A wetness detector as in claim 7, wherein said signal output is in the form of infra-red radiation.

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12. A wetness detector as in claim 7,
wherein said coupling is capacitive, said sensor having
a pair of fixedly spaced planar conductors and said
electrodes having a pair of fixedly spaced pad shaped
conductors respectively capacitively coupled to said
5 planar conductors, one of said pair of conductors being
larger than the other of said conductors to permit
misalignment of said conductors relative to each other
without changing capacitance between said conductors.

10 13. A diaper, comprising:

an absorbent portion;

a liquid resistant portion having first and
second faces and lining the absorbent portion along the
first face;

15 a pouch on the second face of the liquid
resistant portion;

a first electrode extending along said
absorbent portion and projecting along the first face
of the liquid resistant portion opposite the pouch;

20 a second electrode space from the first
electrode and extending along said absorbent portion
and projecting along the first face of the liquid
resistant portion opposite the pouch;

25 said first and second electrodes projecting
along the absorbent portion opposite the pouch and
being insulated from said pouch so as to non-
conductively couple to contents in the pouch.

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14. A diaper as in claim 13, wherein said electrodes have enlarged portions opposite said pouch.

15. A diaper as in claim 13, wherein said electrodes are coated on plastic material.

5 16. A diaper as in claim 13, wherein said electrodes are conductive areas on a water permeable substrate.

17. A diaper as in claim 13, wherein said electrodes are conductive wires.

10 18. A diaper as in claim 13, wherein said electrodes are conductive threads woven into the absorbent material.

15 19. A diaper as in claim 13, wherein said electrodes are printed on said liquid resistant portion.

20. A diaper as in claim 13, wherein said pouch contains a sensor non-conductively coupled to said electrodes.

20 21. A diaper as in claim 13, wherein said pouch contains a sensor capacitively coupled to said electrodes.

25 22. A diaper as in claim 20, wherein said sensor includes a source of varying voltage and an alarm responsive to urine induced lowered resistance between said electrodes.

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23. A diaper as in claim 13, wherein said sensor includes a pair of conductive plate-shaped members opposing said electrodes across said liquid resistant portion.

5 24. A diaper in claim 13, wherein said coupling is capacitive, said sensor having a pair of fixedly spaced planar conductors and said electrodes having a pair of fixedly spaced pad shaped conductors respectively capacitively coupled to said planar
10 conductors, one of said pair of conductors being larger than the other of said conductors to permit misalignment of said conductors relative to each other without changing capacitance between said conductors.

15 25. A wetness detector for placement in a pouch on the outside of a waterproof sheath of the diaper having an absorber and a pair of electrodes extending into the absorber and along the sheath opposite the pouch, comprising:

 a source of varying voltage;

20 a pair of members spaced from each other for placement against the outside of the sheath within the pouch;

 and alarm responsive to detection of low impedance between the conductive members.

25 26. A detector as in claim 25, wherein said alarm is audible.

 27. A detector as in claim 25, wherein said

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alarm is electromagnetic.

28. A detector as in claim 25, wherein said alarm is visible.

5 29. A detector as in claim 25, wherein said alarm is in the form of radio waves.

30. A detector as in claim 25, wherein said alarm is in the form of infrared radiation.

10 31. A detector as in claim 25, wherein said members are plate shaped for capacitive coupling with electrodes in the diaper.

32. A detector as in claim 25, wherein said members are inductive to couple inductively with electrodes in the diaper.

15 33. A detector as in claim 25, further including a housing, said housing having tapered and beveled edges.

34. A detector as in claim 33, wherein said housing includes an extractor tab.

20 35. A detector as in claim 33, wherein said housing includes a spring loaded switch.

36. A detector as in claim 33, wherein said housing has a curved surface.

37. A detector as in claim 25, wherein said alarm produces tactilely-sensible vibrations.

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38. A detector as in claim 25, wherein said alarm is audible.

39. A detector as in claim 25, wherein said alarm is visible.

5 40. A detector as in claim 25, wherein said alarm is electromagnetically detectable.

41. A method of manufacturing a diaper, comprising:

10 forming a liquid-impermeable backing sheet having an exterior surface and an interior surface so as to form an exterior of the diaper and an interior of the diaper;

 bonding a liquid-absorbing arrangement to the interior surface of the backing sheet;

15 bonding an elastic pocket to the exterior surface of the backing sheet to contain a detector module;

20 placing sensing electrodes within the interior of the diaper and within the interior surface of the backing sheet in contact with the liquid absorbing arrangement that is bonded to the backing sheet, and in a direction to extend opposite the elastic pocket that is bonded to the outside of the backing sheet so as to allow the sensing electrodes to
25 couple capacitively to the detector module.

42. A method as in claim 41, wherein bonding

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of the liquid absorbing arrangement includes placing a wetness-absorbing core layer on the water-impermeable layer and placing a water-permeable film layer on the core layer.

5 43. A method as in claim 41, wherein placing
the sensing electrodes includes bonding coupling
electrodes forming a part of the sensing electrodes and
having widened conductive areas on the ends of the
10 sensing electrodes against the interior surface of the
backing sheet opposite the elastic pocket.

 44. A method as in claim 42, wherein bonding
of the liquid absorbing arrangement includes placing a
wetness distributing tissue layer between the backing
sheet and the wetness-absorbing core layer and over the
15 sensing electrodes.

 45. A method as in claim 41, wherein bonding
of the liquid absorbing arrangement includes placing a
wetness-impermeable barrier between portions of the
sensing electrodes and the core layer to define parts
20 of the electrodes to be subject to liquid.

 46. A method as in claim 43, wherein placing
sensing electrodes within the interior of the diaper
and within the interior surface of the backing sheet
includes assembling the sensing electrodes and the
25 coupling electrodes with a sensor carrier and bonding
the sensor carrier to the backing sheet.

 47. A method as in claim 41, wherein placing
sensing electrodes within the interior of the diaper
and within the interior surface of the backing sheet

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includes forming pluralities of pairs of sensing electrodes in a continuous line and separating the pairs of sensing electrodes from the other pairs before placing each pair of sensing electrodes in a diaper.

5 48. A method as in claim 41, wherein placing
sensing electrodes within the interior of the diaper
and within the interior surface of the backing sheet
includes forming the sensing electrodes by selective
removal of continuous conductive coating or converted
10 outer layer from surface of a film material to render
multiple isolated conductive areas from a continuous
piece of coated film.

 49. A method as in claim 41, wherein placing
sensing electrodes within the interior of the diaper
15 and within the interior surface of the backing sheet
includes forming each sensing electrode from a
plurality of parallel filamentary elements.

 50. A method as in claim 41, wherein placing
sensing electrodes within the interior of the diaper
20 and within the interior surface of the backing sheet
includes forming the sensing electrodes of filamentary
elements in contact with flat conductors forming the
coupling electrodes nipped down against the sensing
electrode with the tissue layer nipped down over said
25 sensing and said coupling electrodes and the core layer
nipped down over the tissue layer and the tissue layer
nipped down over the core layer.

 51. A method as in claim 41, wherein placing
sensing electrodes includes placing an electrically
30 conductive material in spaces adjacent the sensing

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electrodes.

52. A method as in claim 41, wherein placing sensing electrodes within the interior of the diaper and within the interior surface of the backing sheet
5 includes incorporating the sensing electrodes within the core layer.

53. A method as in claim 42, wherein placing sensing electrodes within the interior of the diaper and within the interior surface of the backing sheet
10 includes incorporating the sensing electrodes within the core layer and extending the ends of the electrodes outside of the core layer between the core layer and the backing sheet.

54. A method as in claim 41, wherein placing
15 sensing electrodes within the interior of the diaper and within the interior surface of the backing sheet includes forming the sensing electrodes by abrading portions of a conductive layer from a ribbon of non-conductive material carrying a conductive layer.

20 55. A method as in claim 41, wherein placing sensing electrodes within the interior of the diaper and within the interior surface of the backing sheet includes forming the sensing electrodes by placing conductive filaments on an adhesive on a backing layer.

25 56. A method as in claim 41, wherein placing sensing electrodes within the interior of the diaper and within the interior surface of the backing sheet includes forming the sensing electrodes by spin wrapping wire about a yarn.

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57. A method as in claim 41, wherein forming the backing sheet includes forming the backing sheet from two overlying bonded components and treating a portion at the pocket to make the portion at the pocket thinner than the remainder of the backing sheet.

58. A method as in claim 57, wherein treating a portion of the backing sheet at the pocket includes ultrasonic treatment.

59. An apparatus for manufacturing a diaper, comprising:

means for forming a backing sheet having an exterior surface and an interior surface so as to form an exterior of the diaper and an interior of the diaper and including a backing sheet carrier;

a wire feed, braking, and anti-run-on placement device adjacent the backing sheet carrier;

wire directional control pins aligned with said placement device above the backing sheet carrier and in the path of wire passing to said backing sheet;

means for bonding a tissue layer to the interior surface of the backing sheet and wires; and

means for bonding an elastic pocket to the exterior surface of the backing sheet to contain a detector module.

60. An apparatus as in claim 59, wherein said means for bonding a pocket includes a backing

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sheet thinner for making a portion of the backing sheet thinner at the location of the pocket.

61. A wetness detector, comprising:

a source of varying voltage;

5 a pair of conductive members spaced from each other for placement in the vicinity of an area to be tested for wetness;

and alarm responsive to detection of conductance between the conductive members;

10 a counter for counting the number of times wetness is detected.

62. A detector as in claim 61, wherein said alarm is audible.

15 63. A detector as in claim 61, wherein said alarm is visible.

64. A detector as in claim 61, wherein said alarm is both audible and visible.

20 65. A detector as in claim 61, wherein said members are plate shaped for capacitive coupling with electrodes in the area to be sensed for wetness.

66. A detector as in claim 61, further including a housing, said housing having tapered and beveled edges.

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67. A detector as in claim 66, wherein said housing includes an extractor tab.

68. A detector as in claim 66, wherein said housing includes one or more retractable levers.

5 69. A detector as in claim 66, wherein said housing has one or more curved surfaces, where said levers may be spring-loaded.

70. A detector as in claim 61, wherein said alarm is visible.

10 71. A detector as in claim 61, wherein said alarm is visible.

72. A detector as in claim 61, wherein said counter stops detection after a predetermined number of counts.

15 73. A detector as in claim 61, wherein said source includes a signal generator having a duty cycle less than 50%.

20 74. A detector as in claim 61, wherein said source includes a signal generator having a duty cycle less than 1/2000.

75. A detector as in claim 61, wherein said alarm includes an LED blinker circuit.

76. A detector as in claim 61, wherein said alarm includes a piezo tone generator.

25 77. A detector as in claim 61, wherein said

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alarm includes a piezo presence sensor to sense the
presence of a piezo device.

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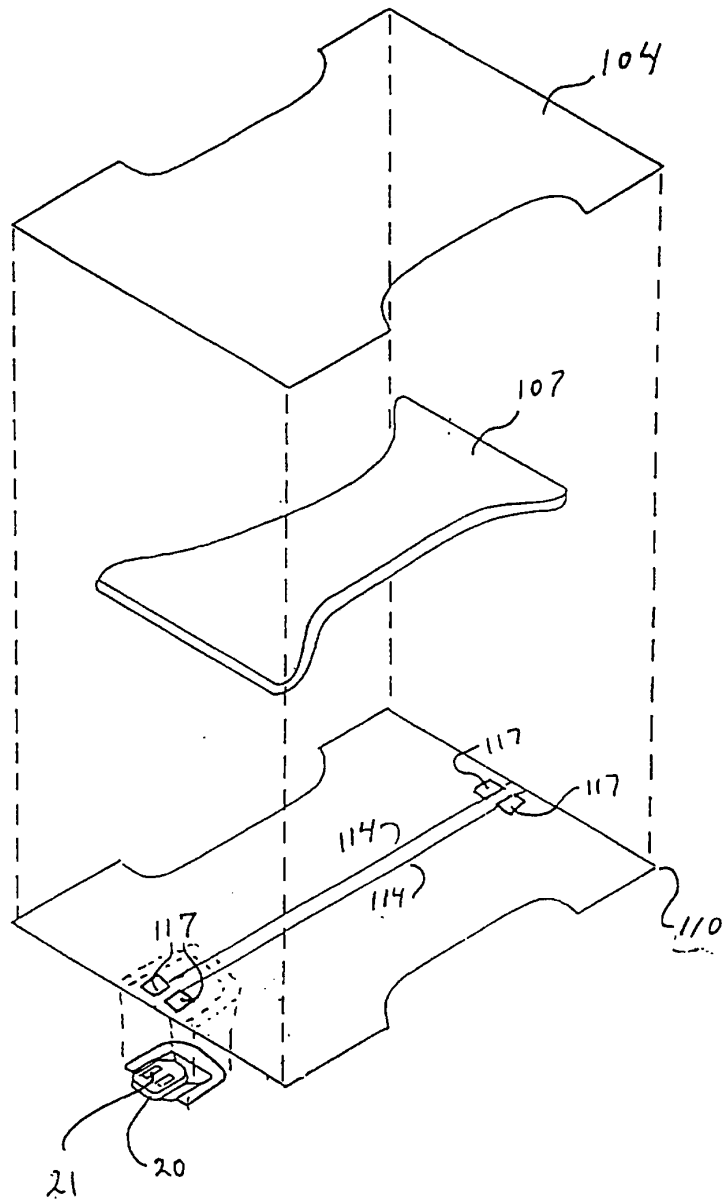


Fig. 1

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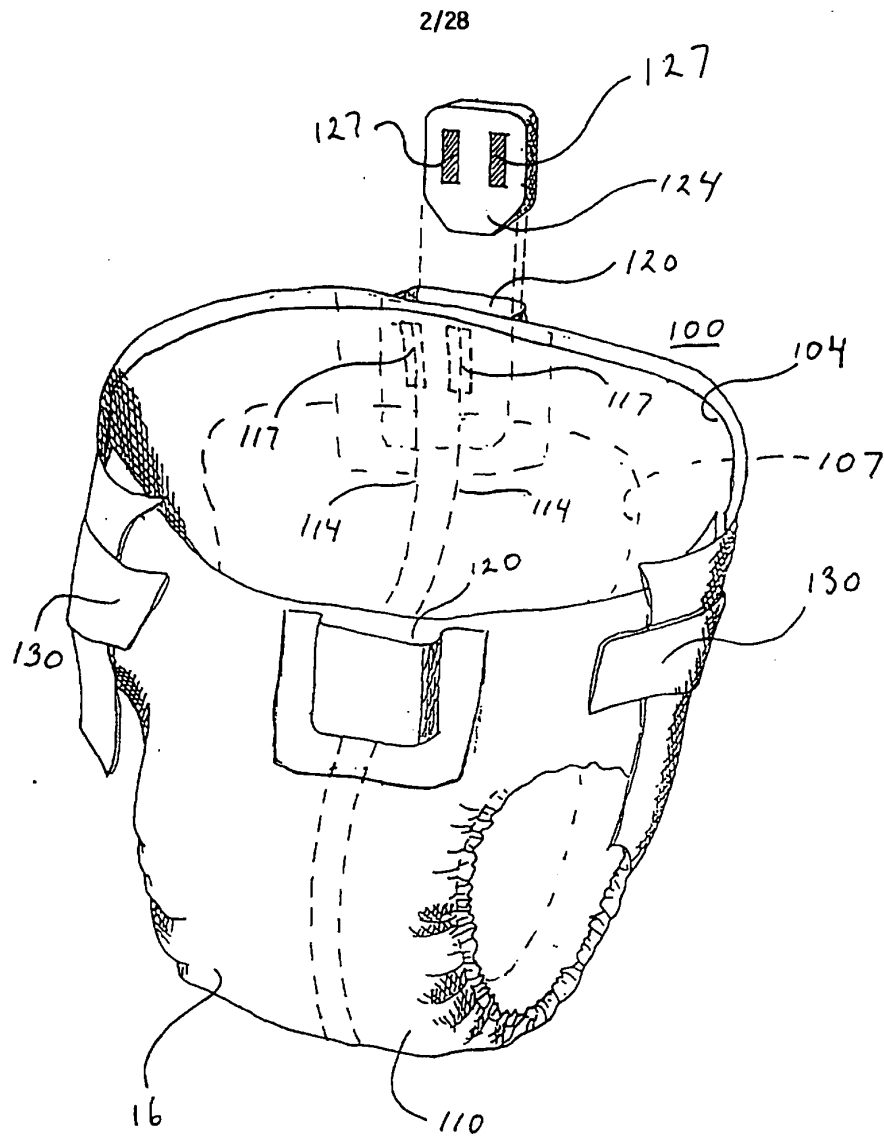
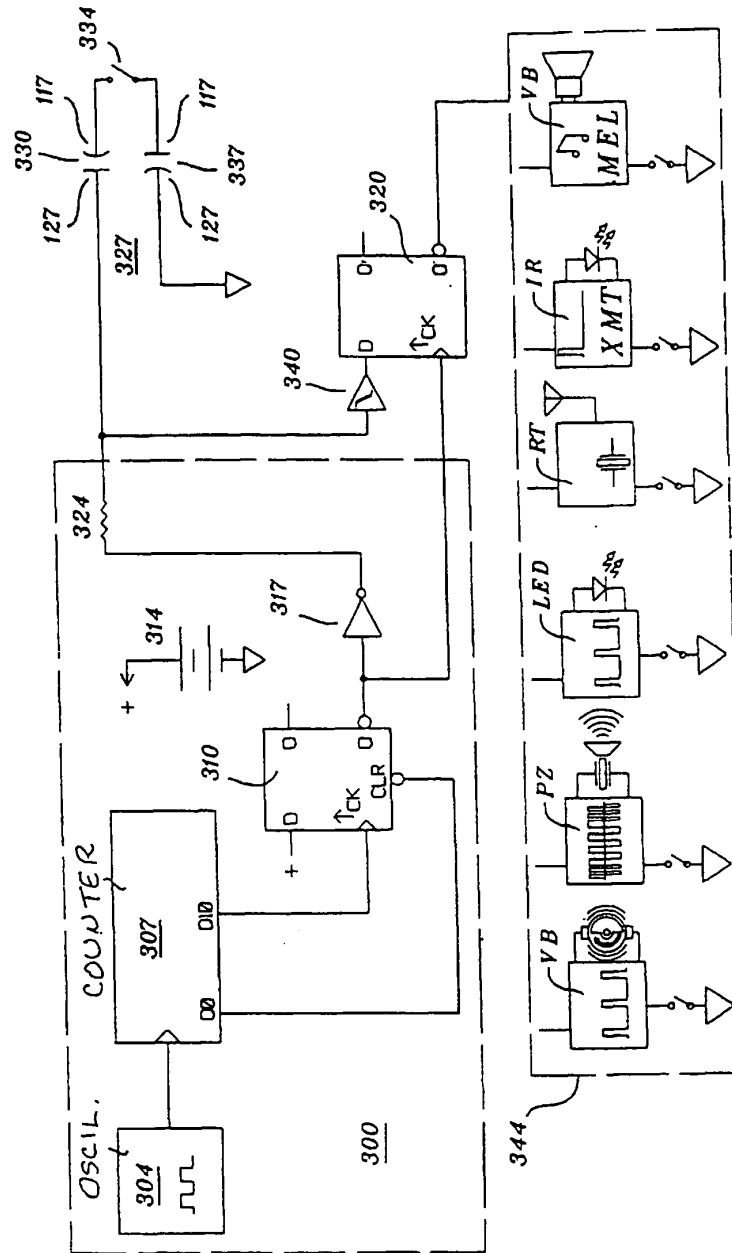


Fig. 2

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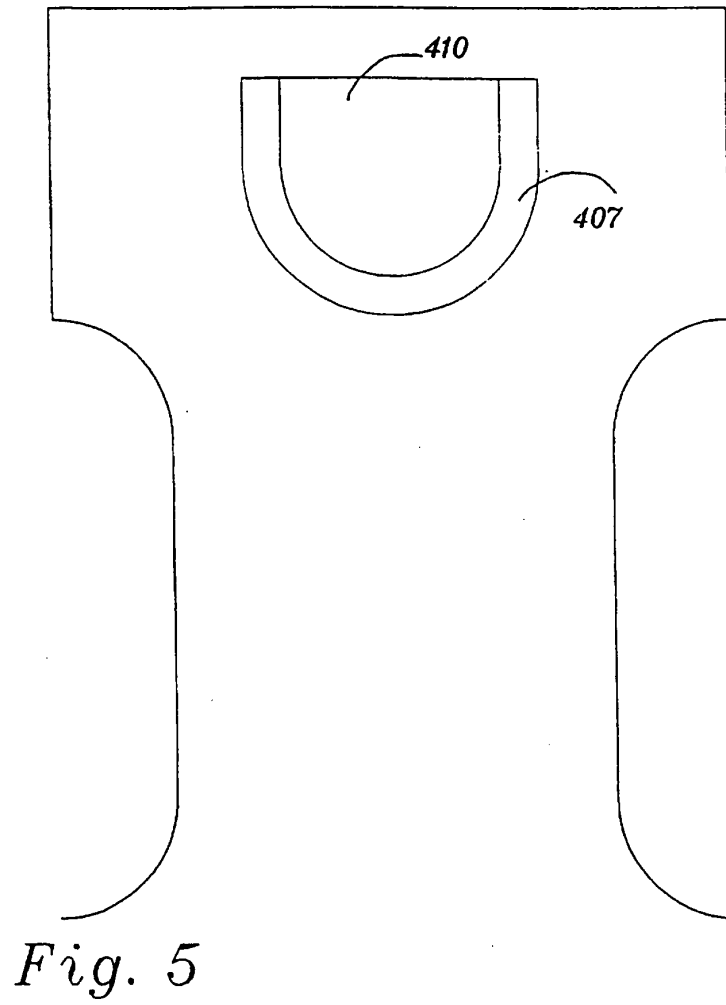
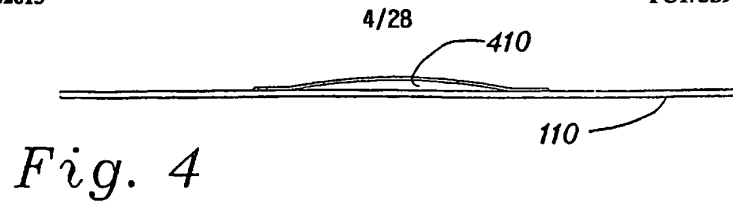
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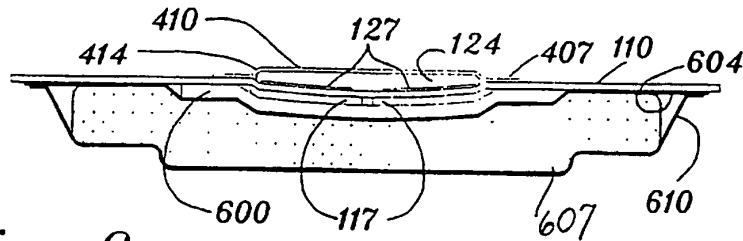


Fig. 6

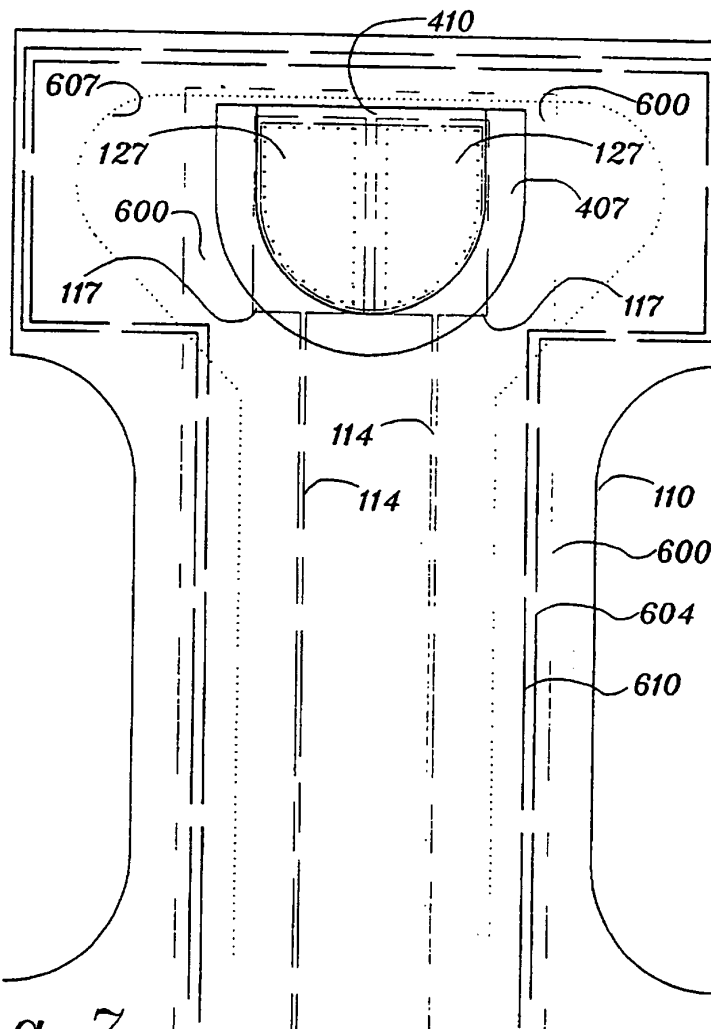


Fig. 7

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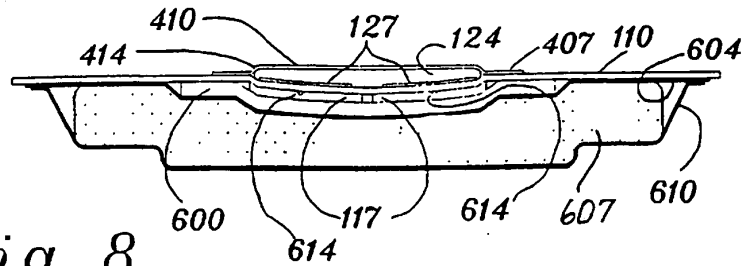


Fig. 8

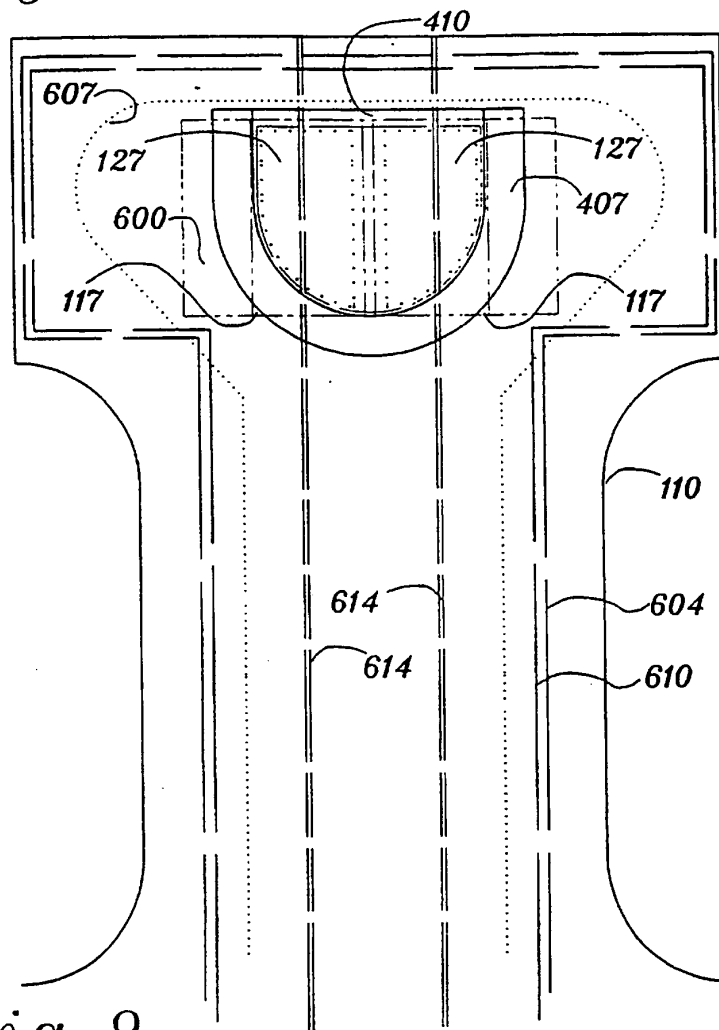


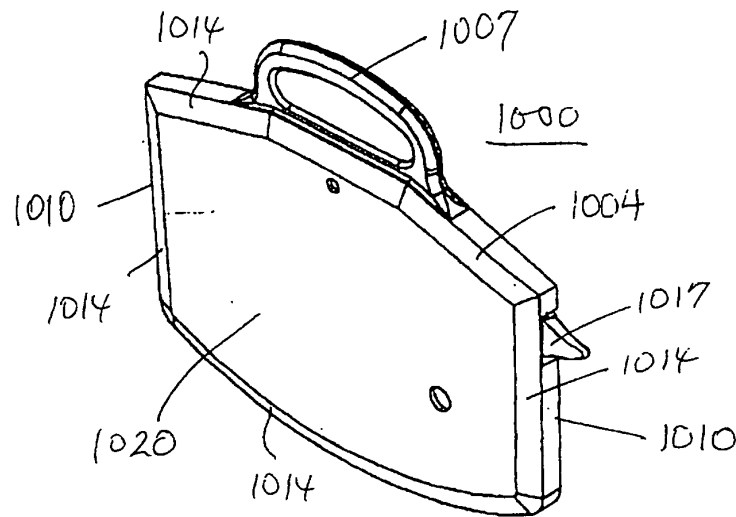
Fig. 9

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Fig. 10

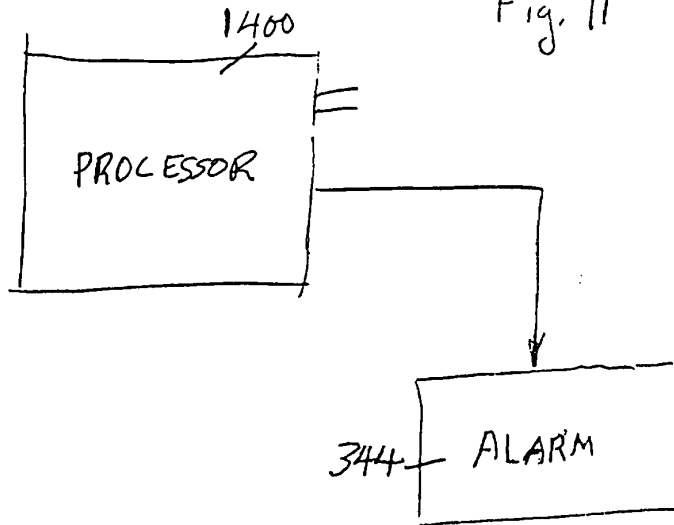


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Fig. 11



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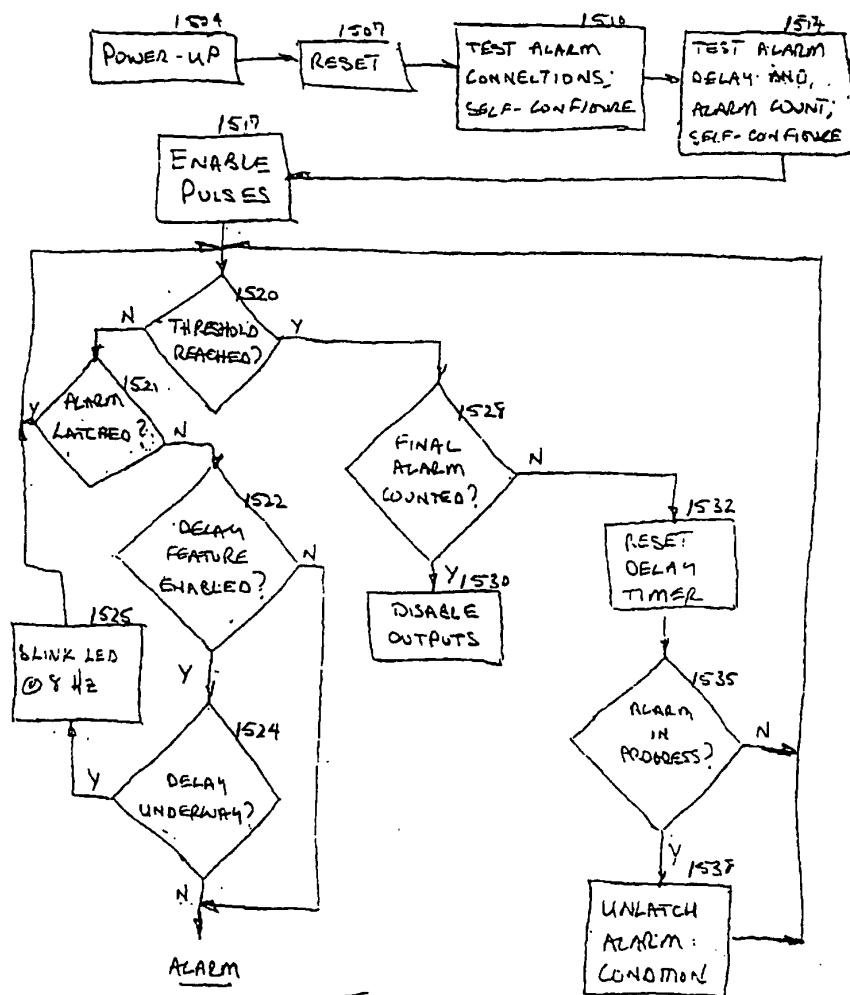


Fig. 12

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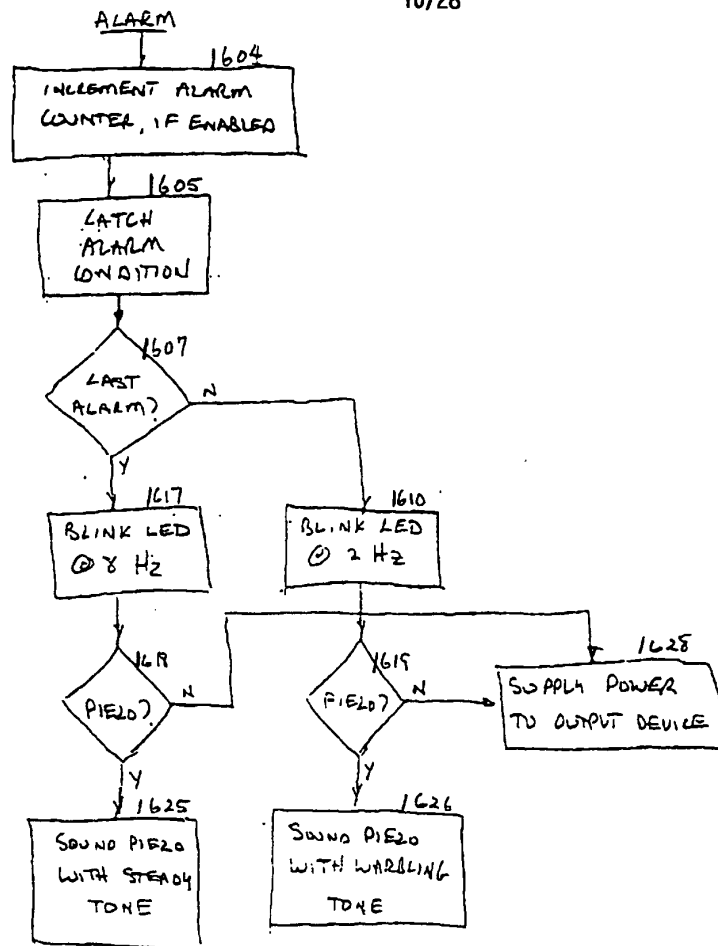
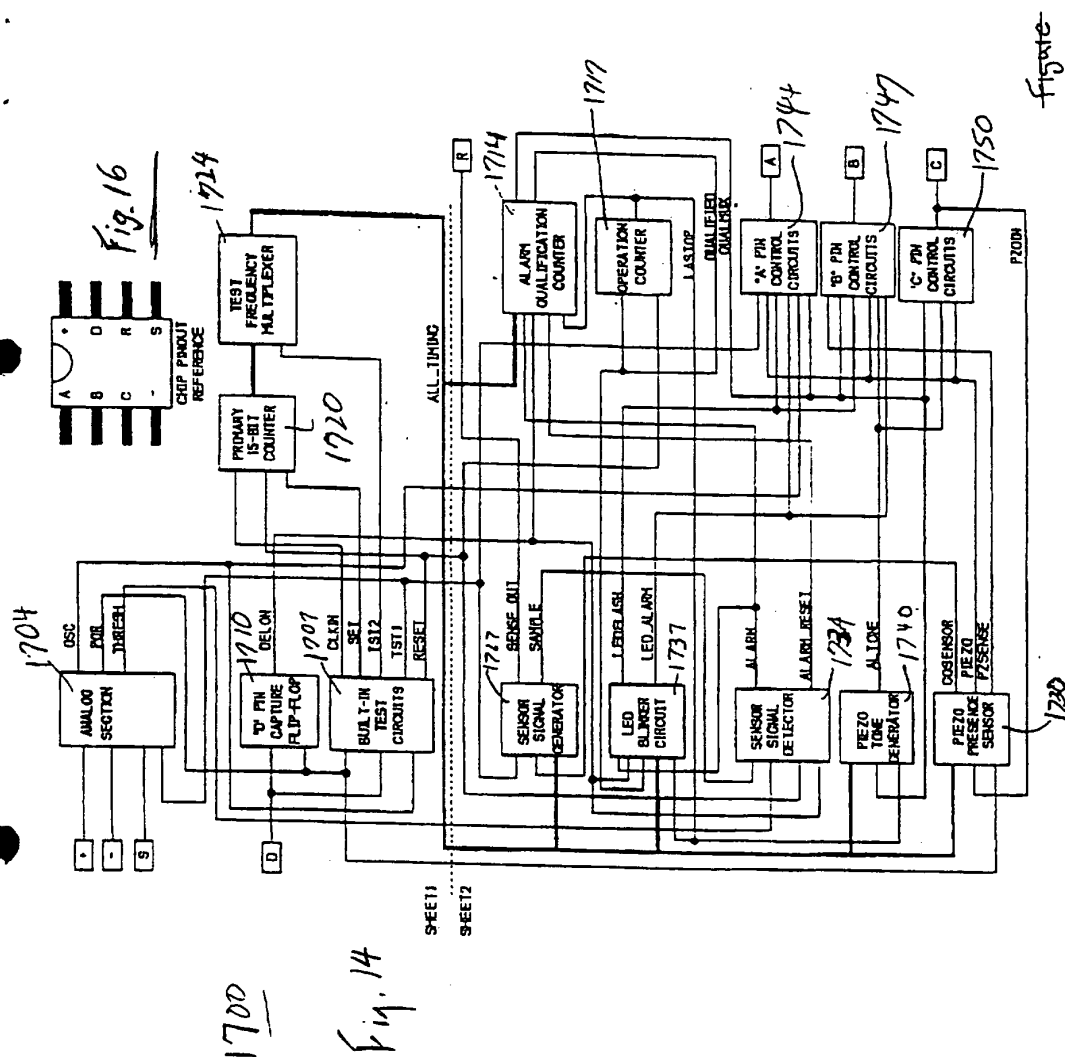


Fig. 13

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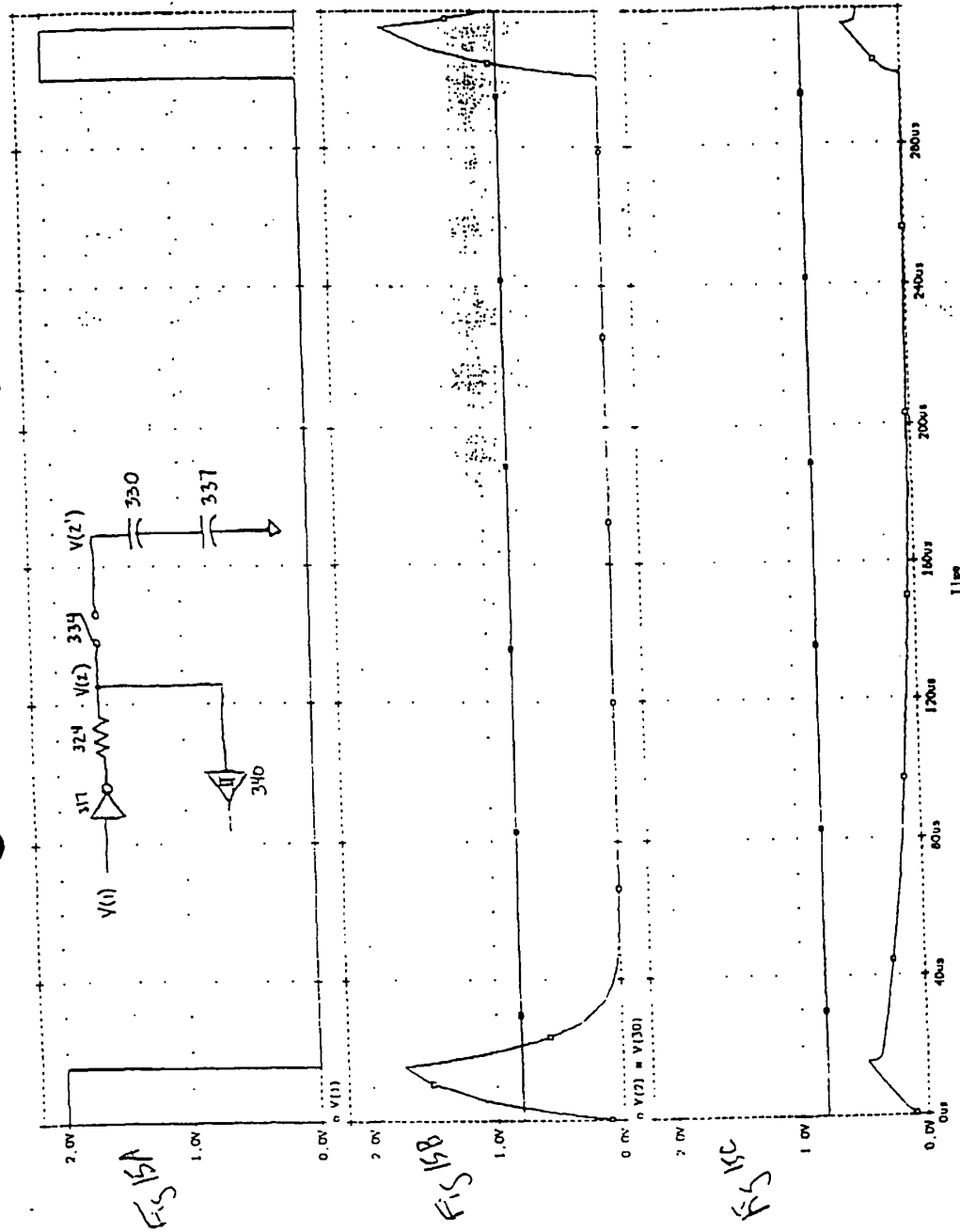
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Fig. 19

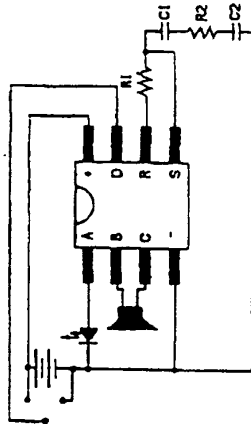


Fig. 18

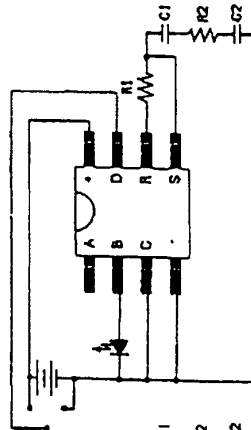


Fig. 17

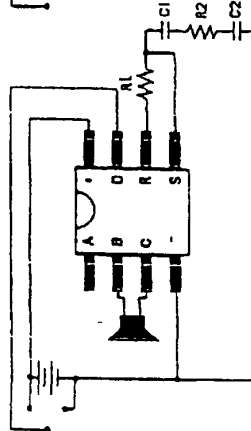


Fig. 20A

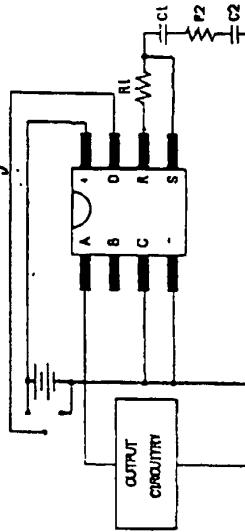
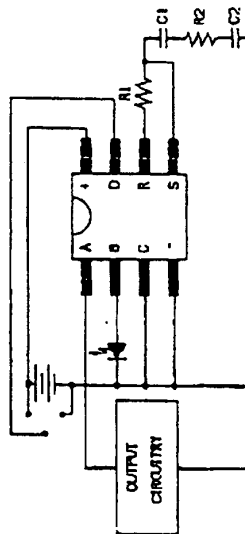


Fig. 20



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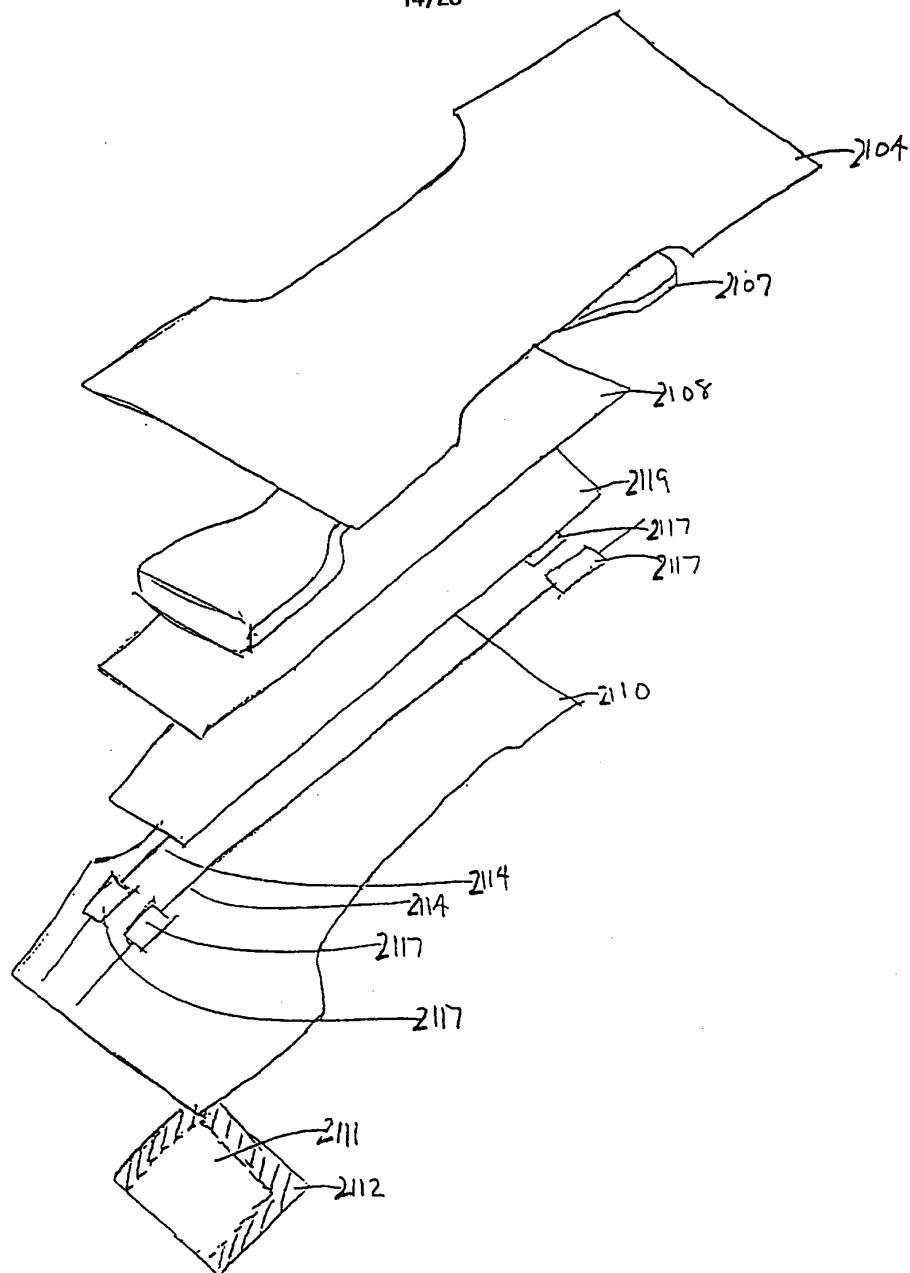


FIG. 21B

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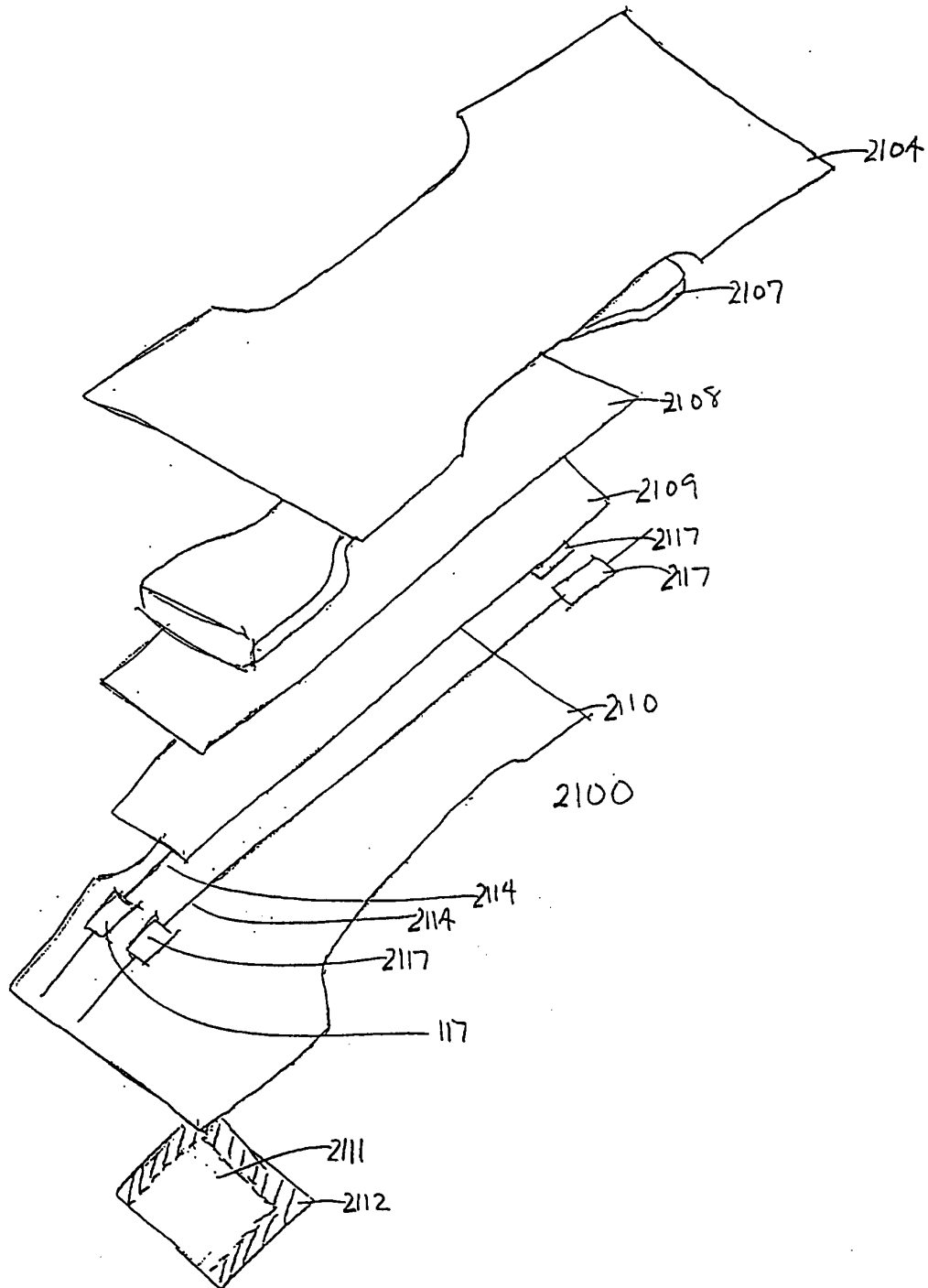


FIG. 21A

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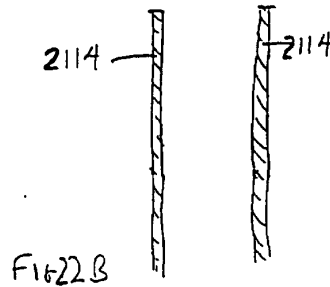
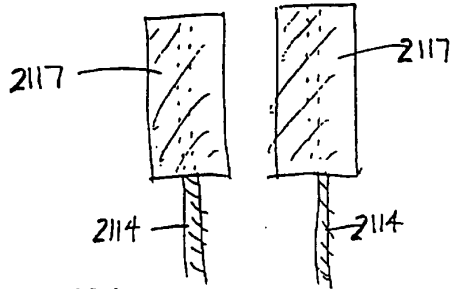
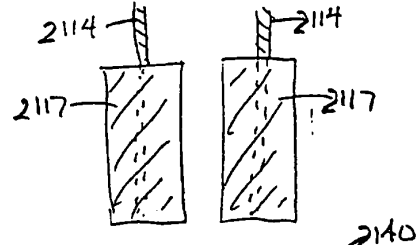
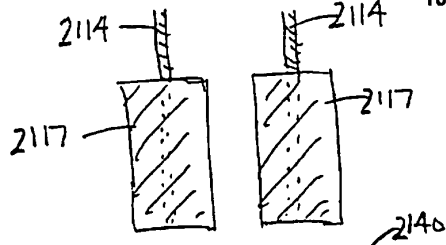


FIG. 22A

FIG. 22B

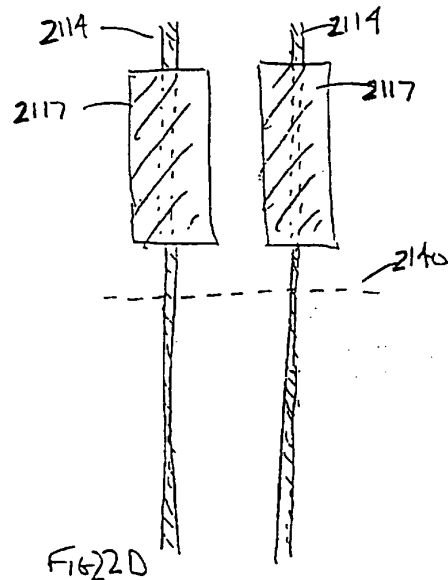
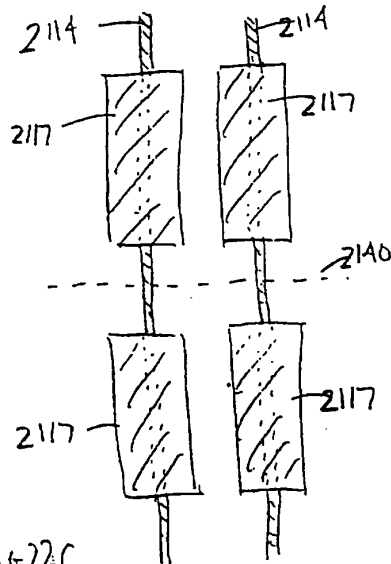


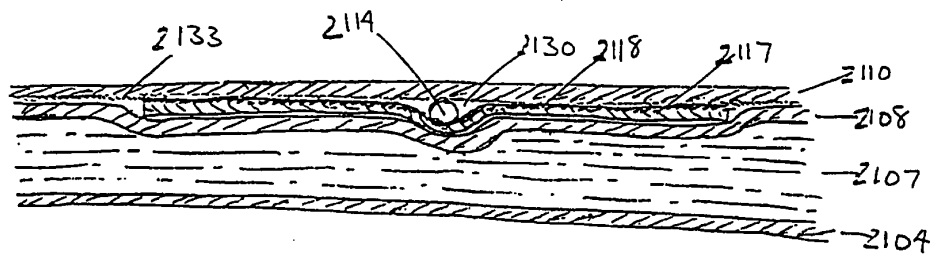
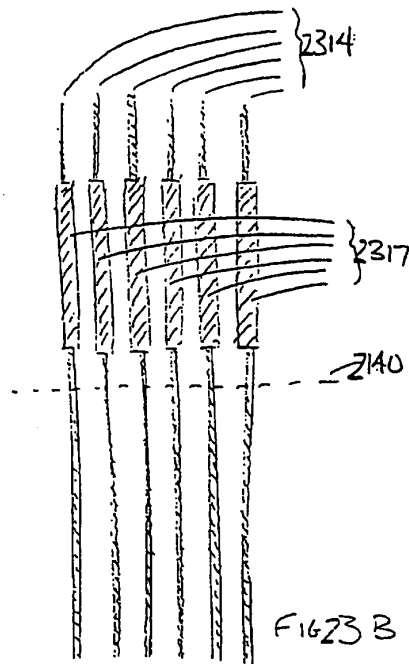
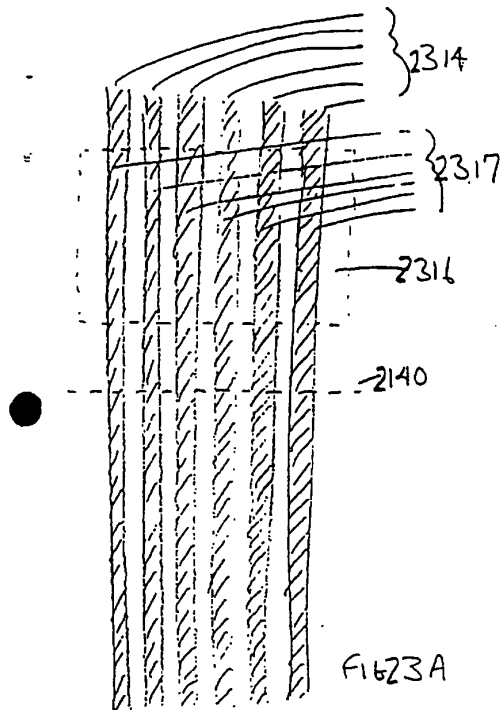
FIG. 22C

FIG. 22D

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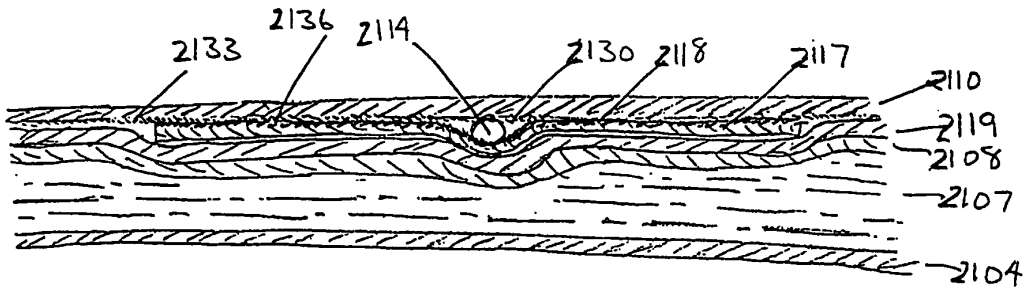


FIG. 25

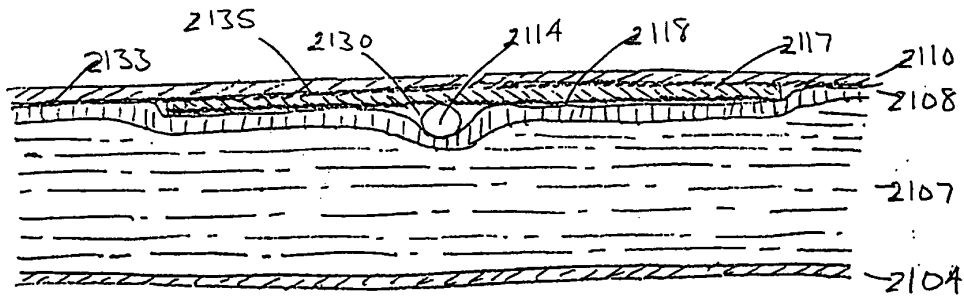


FIG. 26

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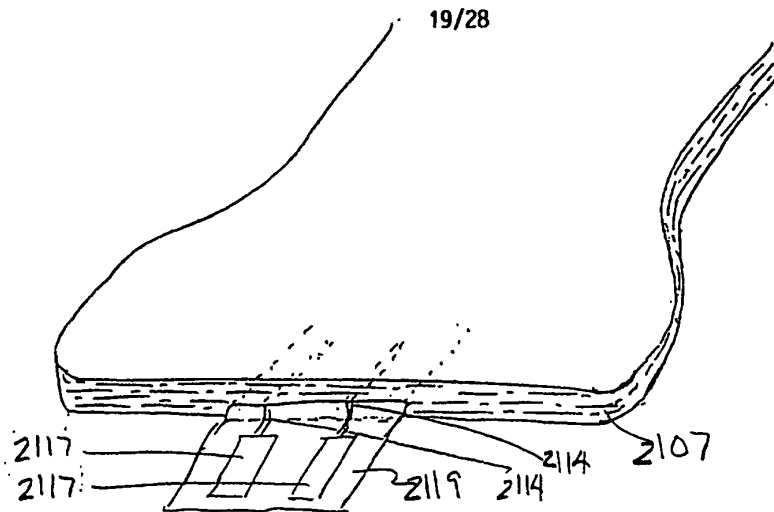


FIG. 27

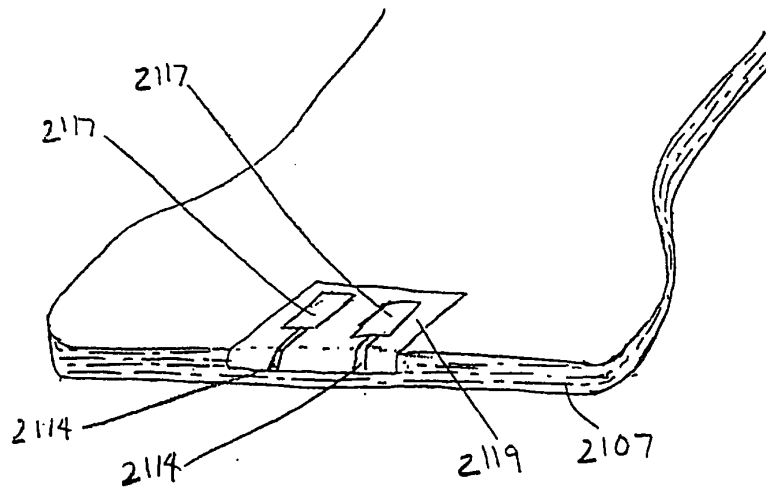


FIG. 28

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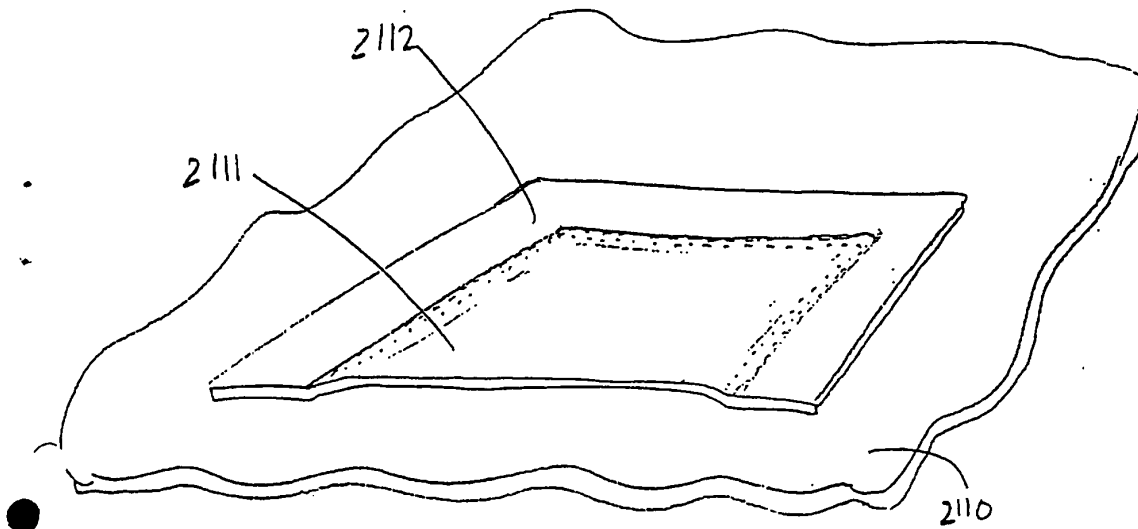


FIG. 29

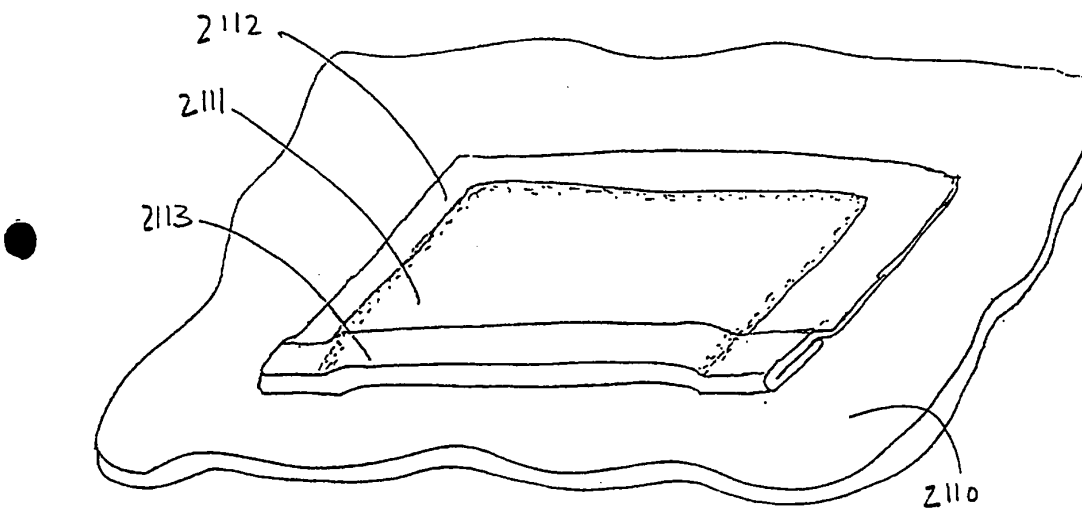


FIG. 30

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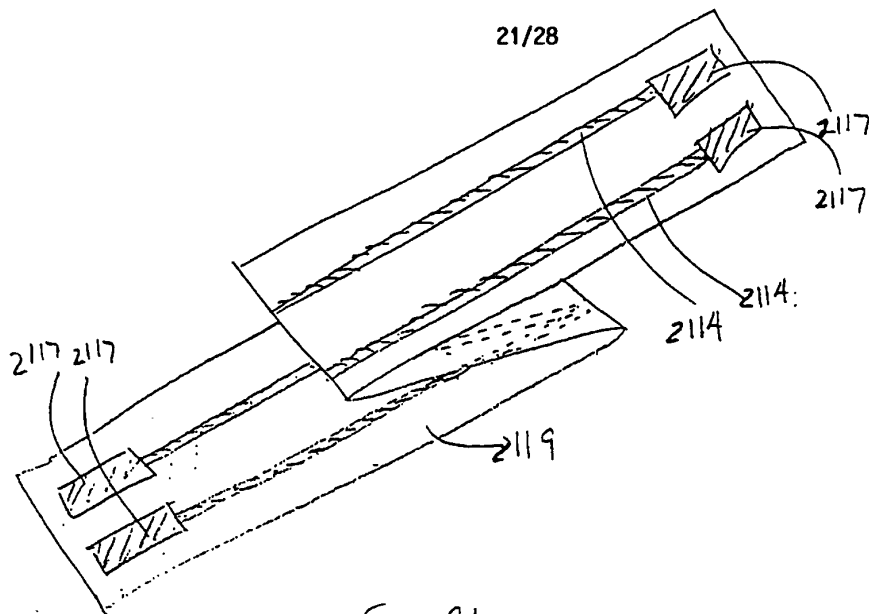


Fig. 31

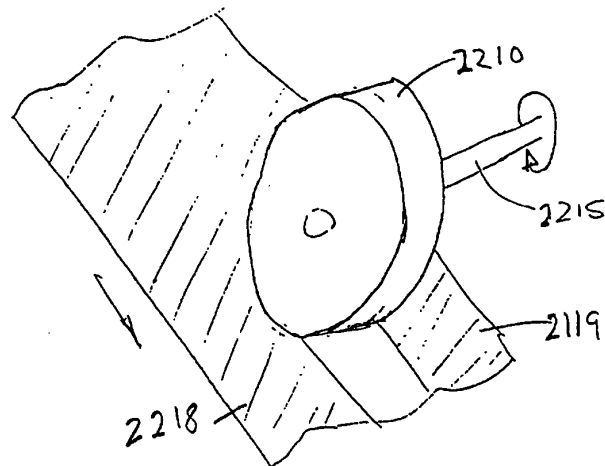


FIG. 32

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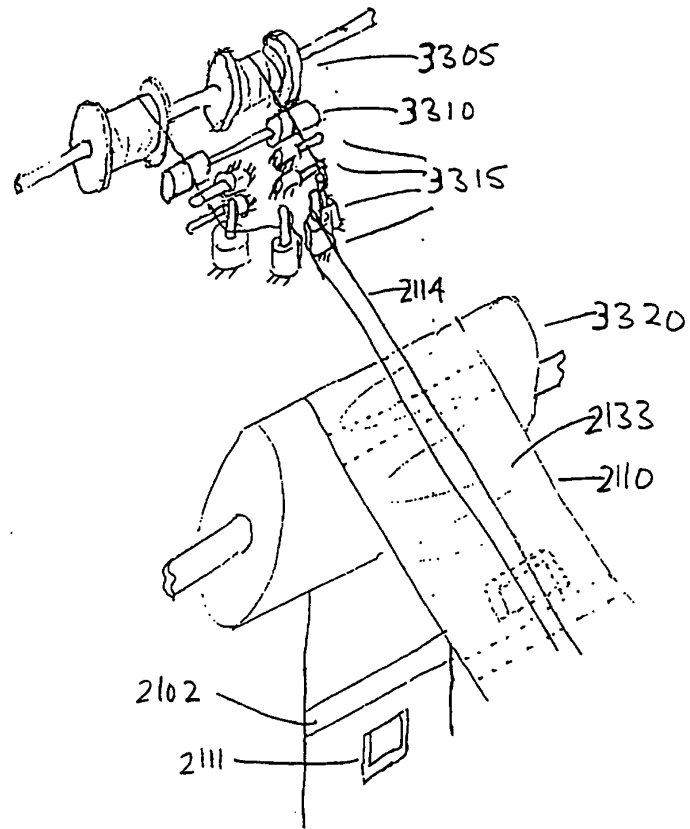


FIG. 33

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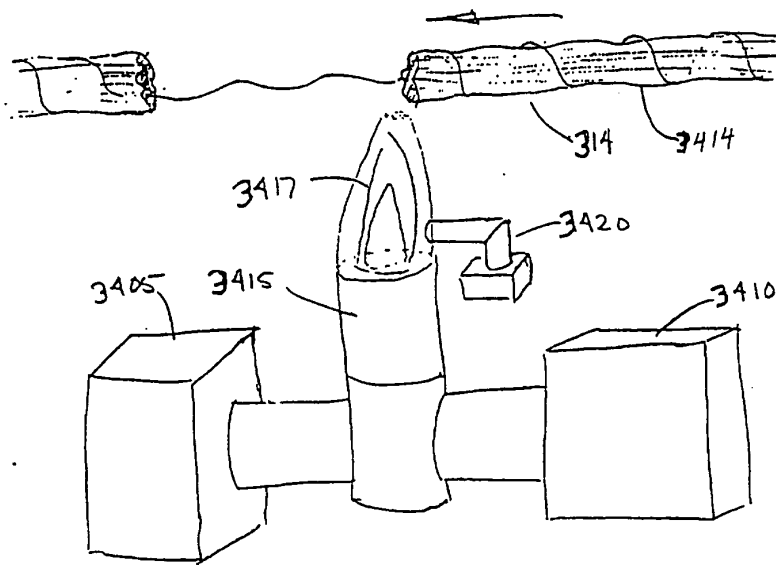
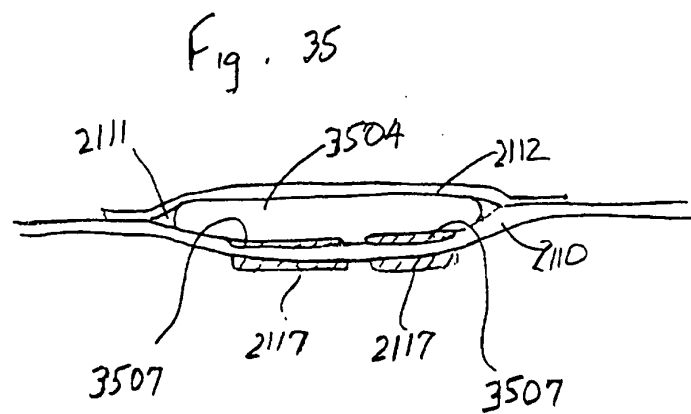


Fig. 34

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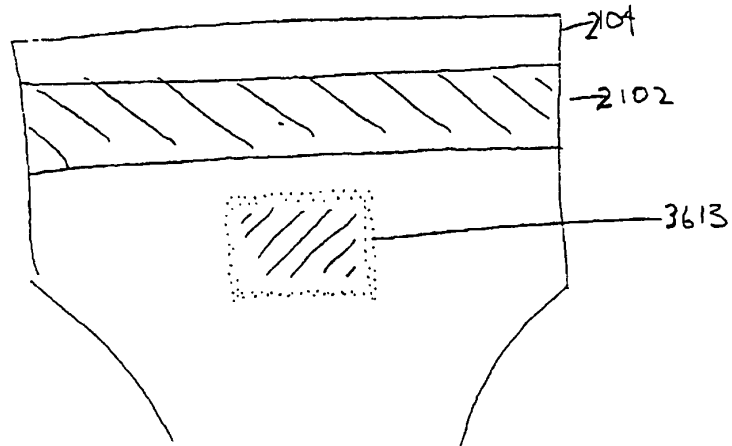


FIG. 36

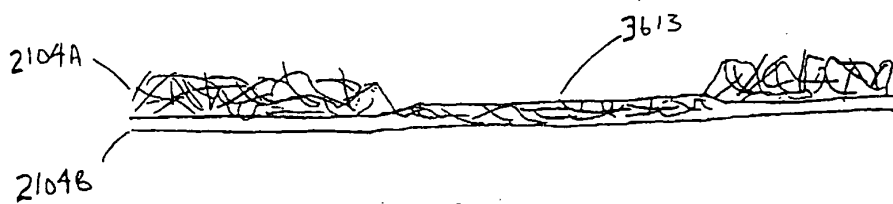


FIG. 37

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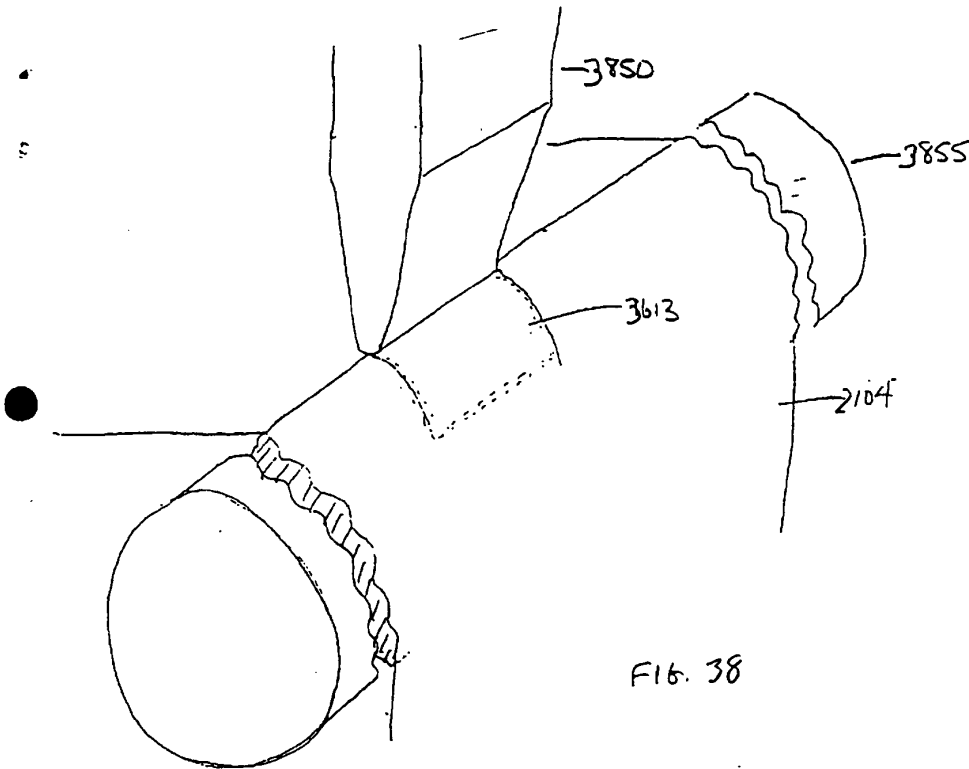


FIG. 38

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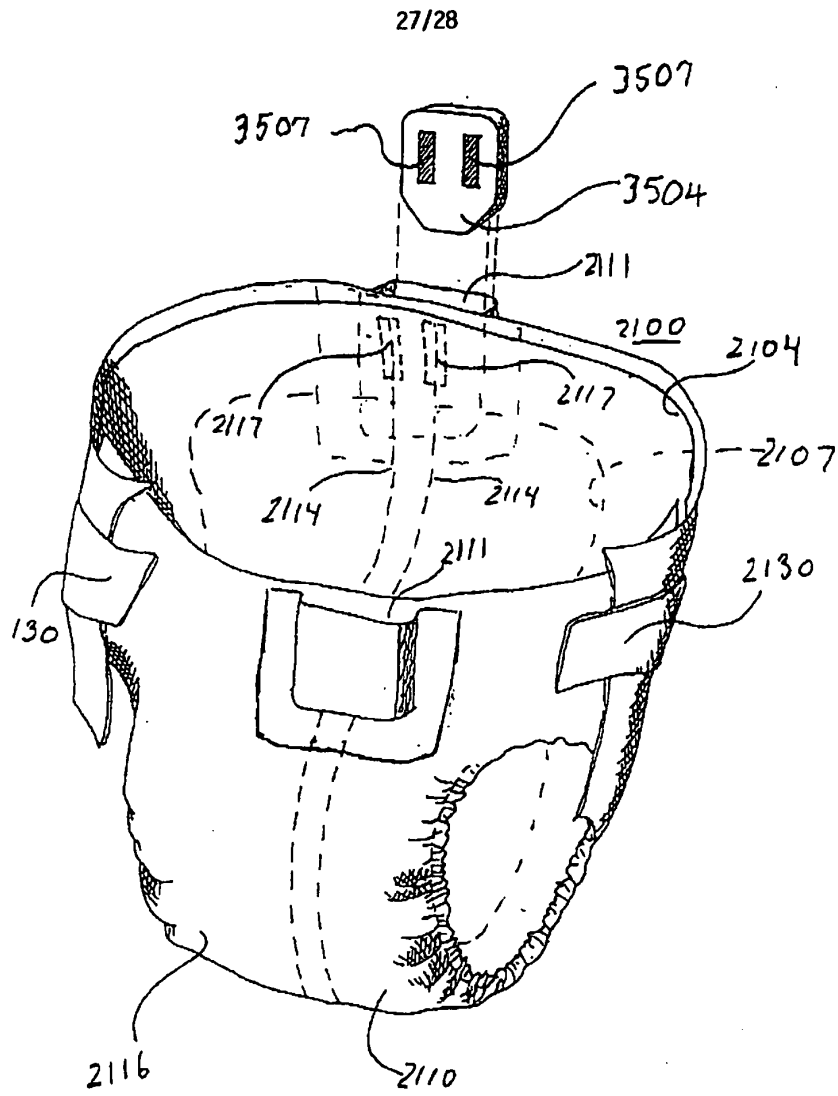


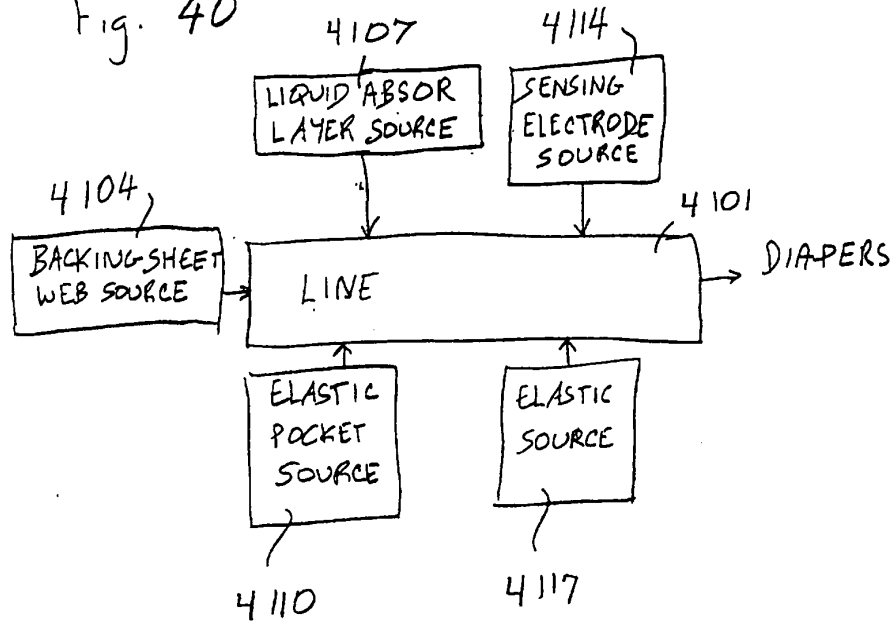
Fig. 39

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Fig. 40



PATENT ABSTRACTS OF JAPAN

(11)Publication number : 09-206292

(43)Date of publication of application : 12.08.1997

(51)Int.Cl.

A61B 5/20

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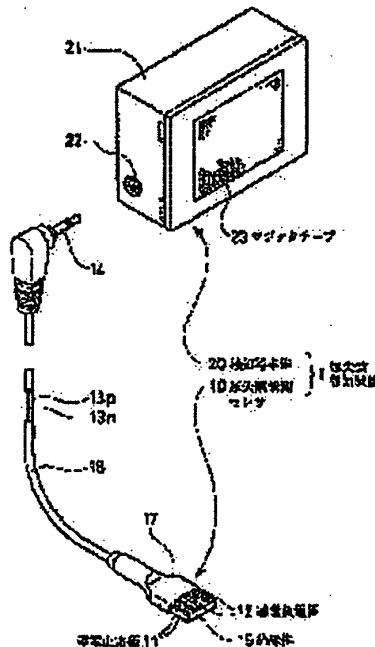
(21)Application number : 08-038828

(71)Applicant : SOATEC:KK

(22)Date of filing : 31.01.1996

(72)Inventor : OZAKI HIROKI

(54) URINARY INCONTINENCE DETECTING SENSOR AND URINARY INCONTINENCE ALARMING DEVICE USING THE SAME



(57)Abstract:

PROBLEM TO BE SOLVED: To provide an urinary incontinence alarming device that is usable a number of times, has not only a simplified structure but also a reduced urine detecting part to eliminate a rugged feel, can save the power consumed, is excellent in corrosion resistance and longevity, prevents detecting errors, and is convenient for carrying around.

SOLUTION: This urinary incontinence alarming device 1 comprises an urinary incontinence detecting sensor 10, having a urine detecting part, and a detector main body 20; in the urine detecting part of the urinary incontinence detecting sensor 10, a plurality of long, conductive positive electrodes 11 and a plurality of long, conductive negative electrodes 12 are spaced alternately and parallel to each other and bonded to an insulator 15, all of the conductive positive electrodes 11 being connected to a positive conductor 13p, and all of the conductive negative electrodes 12 to a negative conductor 13n. Built in the detector main body 20 are an amplifier part for amplifying a urine detection current, a current comparing circuit for producing an alarm current from the urine detection current, an alarm device for issuing an alarm to report urinary incontinence by means of an alarm current, and an intermittent current-carrying circuit for intermittently monitoring whether or not the urinary incontinence detecting sensor 10 carries a shortcircuit current.

LEGAL STATUS

[Date of request for examination]

[Date of sending the examiner's decision of rejection]

[Kind of final disposal of application other than the examiner's decision of rejection or application converted registration]

[Date of final disposal for application]

[Patent number]

[Date of registration]

[Number of appeal against examiner's decision of rejection]

[Date of requesting appeal against examiner's decision of rejection]

[Date of extinction of right]



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26 June 2007 | Page 1

JA0620

Device for detection of bacterial, viral and/or fungal pathogens in infant stools and/or urine comprises test strip inserted into diaper

Publication number: DE19837678

Publication date: 2000-03-02

Inventor: STRECKERT HANS-JUERGEN (DE); TAPPE DIETMAR (DE)

Applicant: RUBITEC GES FUER INNOVATION UN (DE); STRECKERT HANS JUERGEN (DE)

Classification:

- **international:** A61F13/42; C12Q1/04; G01N33/569; A61F13/42; C12Q1/04; G01N33/569; (IPC1-7): G01N33/50; A61F13/15

- **European:** A61F13/42; C12Q1/04; G01N33/569

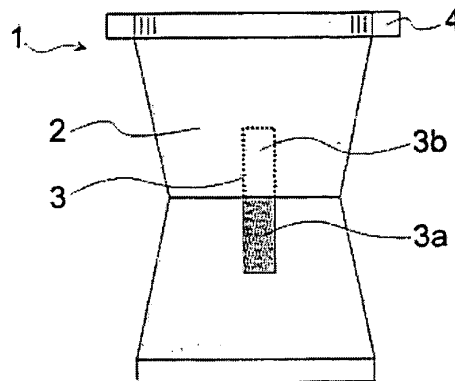
Application number: DE19981037678 19980819

Priority number(s): DE19981037678 19980819

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Abstract of DE19837678

Indicator device for diagnostic detection of bacterial, viral and/or fungal pathogens in stools and/or urine comprises a test strip (3) that has a detection zone (3a) sensitive to specific pathogens and is located beneath a liquid-permeable membrane (2) on the inside of a diaper (1). An Independent claim is also included for a method for diagnostic detection of bacterial, viral and/or fungal pathogens in stools and/or urine, comprising placing the test strip immediately beneath a liquid-permeable membrane on the inside of a diaper, removing the strip after defecation and/or urination, and developing the strip in a rapid assay process.



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①9 **BUNDESREPUBLIK
DEUTSCHLAND**



**DEUTSCHES
PATENT- UND
MARKENAMT**

⑩ **Offenlegungsschrift
DE 198 37 678 A 1**

⑤1 Int. Cl.⁷:
G 01 N 33/50
A 61 F 13/15

②1 Aktenzeichen: 198 37 678.2
②2 Anmeldetag: 19. 8. 1998
④3 Offenlegungstag: 2. 3. 2000

DE 198 37 678 A 1

⑦1 **Anmelder:**

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58452 Witten, DE

⑦2 **Erfinder:**

Streckert, Hans-Jürgen, Dr., 58452 Witten, DE;
Tape, Dietmar, Dipl.-Biol., 44339 Dortmund, DE

⑤6 **Entgegenhaltungen:**

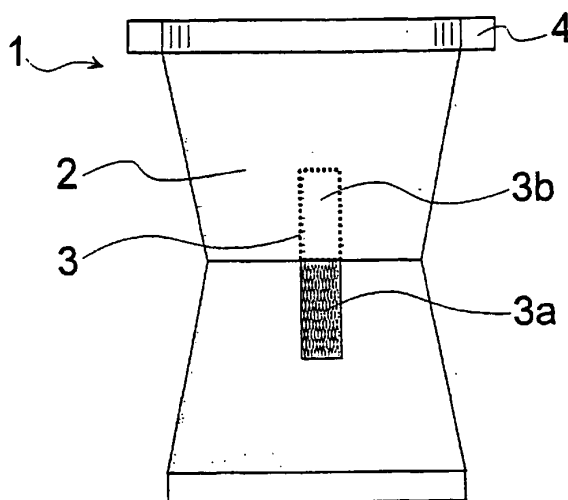
US 54 68 236
US 51 69 757
WO 95 26 161 A1

Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gem. § 44 PatG ist gestellt

⑤4 **Indikatoreinrichtung**

⑤7 Die Erfindung betrifft eine Indikatoreinrichtung zum diagnostischen Nachweis von in Stuhl und/oder Urin enthaltenden bakteriellen und/oder viralen und/oder mykotischen Erregern. Um die Probennahme zu vereinfachen und das Testverfahren als ganzes zu beschleunigen, schlägt die Erfindung vor, daß ein Teststreifen (3) mit einer auf spezifische Erreger sensitiven Detektorzone (3a) in einer Windel (1) anbringbar ist, wobei sich die Detektorzone (3a) unterhalb einer flüssigkeitsdurchlässigen Windelmembrane (2) befindet, die auf der körperzugewandten Innenseite der Windel (1) angeordnet ist.



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Beschreibung

Die vorliegende Erfindung betrifft eine Indikatoreinrichtung zum diagnostischen Nachweis von in Stuhl und/oder Urin enthaltenen, bakteriellen und/oder viralen und/oder mykotischen Erregern.

Mittels entsprechend sensibilisierter Tests lassen sich – beispielsweise bei Verdacht auf gastrointestinale und/oder Harnwegsinfektion – die dann im Stuhl und/oder Urin enthaltenen Erreger nachweisen. Die Konsistenz des Stuhls macht dabei zunächst eine Extraktion der wässrigen Bestandteile durch Zentrifugieren und Filtrieren erforderlich, um eine analysefähige Probe zu erhalten. Urinproben müssen zunächst aufgefangen werden. Die Verwendung von Urinbeuteln ist jedoch beim Kleinkind problematisch.

Bisher bekannte diagnostische Verfahren sehen z. B. die Auswertung der gewonnenen Probensuspension mittels Elisa-Tests unter Verwendung von Titerplatten oder dergleichen vor. Diese Tests sind hochsensibel, allerdings nur unter Laborbedingungen durchführbar.

Gastrointestinale und/oder Harnwegsinfektionen können zu schweren Krankheitsbildern einschließlich lebensgefährdender Zustände führen. Daher ist eine sichere und insbesondere schnelle Diagnosemethode mittels geeigneter Indikatoreinrichtungen hier von besonderer Wichtigkeit. Bislang ist es nach dem Stand der Technik jedoch erforderlich, aus dem – regelmäßig in der Windel anfallenden Stuhl – zunächst eine analysefähige Suspension zu gewinnen. Das wird nicht zuletzt dadurch erschwert, daß Windeln in der Regel bewußt so ausgestaltet sind, daß die im Stuhl anfallende Feuchtigkeit durch eine saugfähige Schicht aufgenommen wird. Urin wird ebenfalls von der Windel aufgesaugt. Die für den Erregernachweis nach bisher üblichen Verfahren notwendige Gewinnung einer Stuhlsuspension oder des Urins aus der Windel unter hygienischen Bedingungen gestaltet sich schwierig.

Das der Erfindung zugrundeliegende Problem liegt angesichts dessen darin, eine Indikatoreinrichtung zur Verfügung zu stellen, die bei Säuglingen einen einfachen, hygienisch vorteilhaften und vor allem raschen Nachweis von Erregern im Stuhl und/oder Urin ermöglicht.

Zur Lösung dieser Problematik wird erfindungsgemäß eine Indikatoreinrichtung vorgeschlagen, bei welcher ein Teststreifen mit mindestens einer auf spezifische Erreger sensitiven Detektorzone in einer Windel anbringbar ist, wobei sich die Detektorzone unterhalb einer flüssigkeitsdurchlässigen Windelmembrane befindet, die auf der körperzugewandten Innenseite der Windel angeordnet ist.

Die Erfindung sieht vor, daß ein Teststreifen, der eine oder mehrere auf spezifische Erreger sensibilisierte Detektorzonen aufweist, unmittelbar in eine Windel integriert wird. Damit erhält man die Möglichkeit, bei Verdacht auf gastrointestinale und/oder Harnwegsinfektionen durch die Benutzung einer erfindungsgemäß ausgestatteten Windel – die man als "Indikatorwindel" bezeichnen könnte – eine hygienische Probenahme zu gewährleisten. Die benetzten Teststreifen können unmittelbar nach der Entnahme in einem Schnelltestverfahren entwickelt werden. Hiermit ist die Diagnose innerhalb weniger Minuten erhältlich. Die damit erreichte Zeitersparnis zu einer herkömmlichen Diagnosestellung nach Einsendung der Probe in ein diagnostisches Labor ist beträchtlich.

Ein besonderer Vorteil der Erfindung besteht darin, daß die Probe zur Diagnose nicht gesondert isoliert und/oder aufgearbeitet werden muß. Die Inkubation erfolgt nämlich quasi "in situ". Hierzu wird ausgenutzt, daß die oberste, das heißt mit dem Körper in Berührung kommende Schicht der Windel in der Regel membranartig ausgeformt ist, um anfal-

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lende Flüssigkeiten möglichst schnell und effektiv von der Körperoberfläche abzuleiten. Feste Bestandteile werden dabei zurückgehalten, wobei die Flüssigkeit in tieferliegende Saugschichten durchgelassen wird. Eine solche Windelmembran kann sowohl als feinmaschiges Gewebe, als auch als durchlässige Folie oder dergleichen ausgeführt sein.

Unmittelbar unter dieser ersten Windelmembrane, und zwar im Bereich des Schrittes, wo Stuhl und Urin naturgemäß anfallen, ist bei der Erfindung der Teststreifen mit seiner empfindlichen Detektorzone installiert. Von dem in die Windel abgegebenen Stuhl gelangt somit wie gewünscht ausschließlich der flüssige Bestandteil auf den Teststreifen. Nach der Entnahme des benetzten Teststreifens kann der Nachweis von Erregern unmittelbar erfolgen. Dazu wird der entnommene Teststreifen in einem entsprechend angepaßten Testverfahren entwickelt.

Der besondere Vorteil der erfindungsgemäßen Indikatoreinrichtung liegt folglich darin, daß die Probenaufbereitung bereits bei der Stuhl- bzw. Urinabgabe innerhalb der Windel erfolgt. Nach der Entnahme des zunächst in die Windel integrierten Teststreifens ist der diagnostische Nachweis erheblich früher als nach dem Stand der Technik möglich. Dies bringt einen erheblichen therapeutischen Vorsprung mit sich und ist überdies auch unter seuchenhygienischen Aspekten besonders vorteilhaft.

Eine Umsetzung der erfindungsgemäßen Indikatoreinrichtung ist grundsätzlich bei allen möglichen Ausführungsformen von Windeln denkbar. Vorzugsweise erfolgt jedoch die Anbringung eines Teststreifens in einer Einweg-Windel. Die am Markt erhältlichen Produkte sind nämlich insoweit durchentwickelt, daß durch eine unterhalb der innersten Windelmembrane angebrachte Saugschicht bei der Stuhlabgabe auftretende Flüssigkeit sicher aufgenommen und gebunden wird. Durch die erfindungsgemäße Anordnung des Teststreifens zwischen der Windelmembrane und der Saugschicht erfolgt die Benetzung der Detektorzone, bevor die Flüssigkeit durch die Saugschicht aufgenommen wird. Die Funktion der Windel wird dadurch also nicht beeinträchtigt. Zugleich ist durch die eingesetzten, hochwertigen Membranwerkstoffe gewährleistet, daß die Detektorzone nicht durch feste Stuhlbestandteile verunreinigt wird.

Zweckmäßigerweise hat die Windel eine flüssigkeitsdichte Außenschicht.

Die Handhabung einer erfindungsgemäß ausgestalteten Windel wird dadurch erleichtert, daß der Teststreifen manuell lösbar befestigt ist. Damit kann dieser zur Analyse ohne Hinzunahme von Werkzeug oder dergleichen einfach entnommen werden. Diesbezüglich sieht eine besonders bevorzugte Lösung vor, daß der Teststreifen einen Handhabungsabschnitt aufweist, der in eingesetzten Zustand nach außen über die Windel vorsteht. Das bedeutet, daß der Teststreifen durch die Saugschicht und gegebenenfalls die flüssigkeitsdichte Außenschicht so nach außen herausgeführt ist, daß er entnommen werden kann, ohne dem Säugling die Windel vorher abnehmen zu müssen. Dadurch ist eine Kontamination durch andere Stuhlbestandteile praktisch ausgeschlossen.

Zweckmäßigerweise erfolgt die Fixierung des in der vorangehend erläuterten Weise angebrachten Teststreifens dadurch, daß der Handhabungsabschnitt auf der Außenseite der Windel abtrennbar befestigt ist. Hierzu kann der Teststreifen selbst mit einer von Hand abreißen Perforation versehen sein oder beispielsweise auch mit einem abreißen Klebepunkt auf der Außenschicht der Windel fixiert sein. Damit wird gewährleistet, daß der Teststreifen nicht unbeabsichtigt herausfällt oder verloren geht.

Alternativ kann die Außenschicht der Windel ein manuell auftrennbares Entnahmefenster für den Teststreifen aufwei-

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sen. Bei dieser Ausführungsform ist der Handhabungsabschnitt des Teststreifens zugänglich, nachdem die Außenhaut der Windel von Hand aufgerissen worden ist. Im Bereich der Entnahmeöffnung ist die Außenschicht zweckmäßigerweise so präpariert, daß dies problemlos möglich ist.

Vorzugsweise wird die Detektorzone des Teststreifens sensitiv bezüglich Erregern von gastrointestinalen und/oder Harnwegsinfektionen ausgebildet.

Damit sind sowohl bakterielle Erreger, wie beispielsweise Salmonellen, Streptokokken, Staphylokokken, Colibakterien und dergleichen, als auch virale Erreger wie Enteroviren, Rotaviren, Adenoviren, Astroviren oder dergleichen zu verstehen. Durch eine Abstimmung der Empfindlichkeit auf bestimmte, klinisch relevante Erreger von gastrointestinalen und/oder Harnwegsinfektionen kann rasch eine erste diagnostische Einordnung erfolgen.

Die Diagnose wird dadurch beschleunigt, daß der Teststreifen in einem Schnelltestverfahren auswertbar ist.

Die Erfindung eröffnet grundsätzlich die Möglichkeit durch die erfindungsgemäße Anordnung alle möglichen Formen von Teststreifen für die unterschiedlichsten Erreger klinisch relevanter Symptome besonders vorteilhaft zum Nachweis der Erreger im Frühstadium einer Infektion zu verwenden. Über die Diagnose von bakteriellen und/oder viralen Infektionen hinaus ist grundsätzlich auch der Nachweis von Mykosen durch entsprechend sensibilisierte Teststreifen denkbar.

Wie dargelegt worden ist, ist die Verwendung erfindungsgemäßer Teststreifen zum Nachweis von Mikroorganismen in der besonderen Anwendung der Indikatorwindel besonders vorteilhaft. Der Einsatz solcher Teststreifen ist jedoch keinesfalls auf diesen Zweck beschränkt, sondern kann beispielsweise auch in der Umwelttechnik, bei der Lebensmittelverarbeitung oder zur allgemeinen Hygieneüberwachung erfolgen. Dazu wird die Detektorzone der Teststreifen beispielsweise auf Salmonellen oder Legionellen sensibilisiert.

Der Teststreifen weist eine Testmembrane mit einer Detektorzone auf, die mit erreger-spezifischen Fängerantikörpern und Hilfsreagenzien vorbehandelt ist. Die Herstellung der Testmembrane erfolgt, indem sie zunächst mit ca. 0,2 µg Fängerantikörper belegt und getrocknet wird. Eine Reaktionskontrolle wird dabei mitgeführt.

Das Schnelltestverfahren zur Auswertung einer benetzten Testmembrane sieht vor, daß diese zunächst für etwa zwei Minuten in eine Detektorantikörperlösung (Peroxidase – markierter Antikörper) getaucht wird – oder alternativ mit Antikörperlösung betropft wird. Nach Auswaschen für 15 sek. in Waschlösung wird die Testmembrane ca. 30 sek. in Substratlösung getaucht und sofort abgelesen.

Statt des Eintauchens in Substratlösung erfolgt bei Verwendung eines biotinylierten Antikörpers zunächst ein Eintauchen in eine Extravidinperoxidase-Lösung für zwei Minuten. Danach erfolgt dann die Behandlung mit Waschlösung und Substratlösung, worauf abgelesen werden kann.

Ein Ausführungsbeispiel des erfindungsgemäßen Teststreifens zur Diagnose von gastrointestinalen Infektionen lautet folgendermaßen:

Verwendete Reagenzien:

Membran:

Pall Nylon 66 Biodyne B, 0,45 µm

Beschichtung:

– ca. 0,2 µg Fängerantikörperlösung und 6 µg/ml Glukoseoxidase in PBS (Glukoseoxidase Sigma: G 6891)

pro Spot aufgeben und trocknen lassen

– Absättigen mit 1% hydrolysierte Gelatine (Sigma) in 0,01 mol/l K₃PO₄; 0,15 mol/l NaCl (Zusatz 0,01% Thimerosal) innerhalb 1 h bei RT

Verwendete Antikörper:

Rotavirusnachweis:

10 Monoklonaler Fängerantikörper Ro-F
Markierter monoklonaler Detektorantikörper Ro-D

Adenovirusnachweis:

15 Kaninchen Fängerserum Ad-Rb
Markierter monoklonaler Detektorantikörper Ad-D

Waschpuffer:

20 0,01 mol/l K₃PO₄; 0,15 mol/l NaCl unter Zusatz von 0,05% Tween 20 (Sigma)

Substrat:

25 0,39 mol/l TMB (94 mg/l), 0,55 mol/l Glukose in 30% Methanol,
0,035 mol/l Zitronensäure und 0,035 mol/l Na-phosphat, pH 5,0 (TMB: Sigma T 2885).

30 Eine Ausführungsform einer erfindungsgemäß ausgestalteten Windel wird im folgenden anhand der Zeichnungen näher erläutert. Darin zeigen im einzelnen

Fig. 1 eine Ansicht auf die Innenseite einer Einweg-Windel;

35 Fig. 2 einen Querschnitt durch eine Windel gemäß Fig. 1 im angelegten Zustand in seitlicher Ansicht.

Fig. 1 zeigt einen Blick auf die Innenseite einer erfindungsgemäßen Windel, die ausgebreitet dargestellt und als Ganzes mit dem Bezugszeichen 1 versehen ist. Diese ist bevorzugt als Einweg-Windel ausgebildet.

Die in dieser Darstellung oben liegende, beim Anlegen dem Körper zugewandte, flüssigkeitsdurchlässige Windelmembrane 2 ist in der Zeichnung schematisch gerastert dargestellt.

Unmittelbar unterhalb der Windelmembrane 2 ist in dem Bereich, in dem üblicherweise die Stuhl- und Urinabgabe erfolgt, ein Teststreifen 3 angeordnet. Dieser hat eine – hier schraffiert dargestellte – Detektorzone 3a, die auf medizinisch relevante, bakterielle und/oder virale Erreger sensibilisiert ist.

Der Teststreifen 3 weist weiterhin einen sich an der Detektorzone 3a anschließenden Handhabungsabschnitt 3b auf, der hier gestrichelt eingezeichnet ist. Dieser Handhabungsabschnitt 3b steht über die Außenseite der Windel 1, in dieser Darstellung also auf der Unterseite, nach außen vor.

Zum Anlegen der Windel 1 ist sie mit Befestigungsmitteln 4, wie Klettverschlüssen und dergleichen oder Adhäsionsklebestreifen versehen und weist gegebenenfalls elastische Bündchen oder dergleichen auf.

Fig. 2 zeigt eine Windel 1 gemäß Fig. 1 in angelegtem Zustand, wobei dieselben Bezugszeichen Verwendung finden. Darin ist deutlich erkennbar, wie der Teststreifen 3 mit seiner Detektorzone 3a unmittelbar unterhalb der flüssigkeitsdurchlässigen Windelmembrane 2 liegt.

Unterhalb der Windelmembrane 2 weist die Windel 1 eine flüssigkeitsaufnehmende Saugschicht 5 auf, beispielsweise ein Vlies oder dergleichen, die nach außen hin mit einer flüssigkeitsdichten Außenschicht 6, beispielsweise einer Folie

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oder dergleichen abschließt.

Die Abbildung in Fig. 2 zeigt besonders deutlich, wie der Teststreifen 3 durch die Saugschicht 5 und die Außenschicht 6 mit seinem Handhabungsabschnitt 3b nach außen herausgeführt ist. Dieser ist dort mit einer Perforation oder einem Klebepunkt manuell lösbar auf der Außenschicht 6 fixiert. Diese Verbindung kann im Bedarfsfall leicht von Hand aufgetrennt werden, so daß der Teststreifen 3 nach hinten aus der Windel 1 herausgezogen werden kann, was mit den gestrichelten Pfeilen angedeutet ist.

Die Handhabung der Erfindung erfolgt, indem bei Verdacht auf eine gastrointestinale und/oder Harnwegsinfektion eine Windel 1 wie gewohnt angelegt wird. Bei der Stuhl- und Urinabgabe werden die festen Stuhlbestandteile von der Windelmembrane 2 zurückgehalten, so daß die extrahierte, gegebenenfalls die bakteriellen und/oder viralen Erreger enthaltene Suspension auf die Detektorzone 3a des Teststreifens 3 gelangt. Die überschüssige Flüssigkeit wird wie üblich von der Saugschicht 5 aufgenommen.

Die Detektorzone 3a des Teststreifens 3 ist mit erregerspezifischen Fängerantikörpern und Hilfsreagenzien vorbehandelt.

Unmittelbar nach der Stuhl- bzw. Urinabgabe wird der Handhabungsabschnitt 3b von Hand von der Außenschicht 6 abgetrennt und der benetzte Teststreifen 3 aus der Windel herausgezogen. Die der ausgeschiedenen Flüssigkeit ausgesetzte Detektorzone 3a wird nun in einem Schnelltest entwickelt, so daß innerhalb kürzester Zeit ein Erregernachweis möglich ist.

Die erfindungsgemäße Windel 1 ermöglicht somit eine besonders rasche, unkomplizierte Probennahme. Eine aufwendige Aufbereitung der Probe zur Gewinnung einer analysfähigen Suspension ist nämlich nicht mehr erforderlich. Durch entsprechende Schnelltests ist im Verdachtsfall eine Diagnose auch von medizinischen Laien zu Hause oder ambulant durchführbar, so daß gegebenenfalls schnelle therapeutische Maßnahmen eingeleitet werden können.

Patentansprüche

1. Indikatoreinrichtung zum diagnostischen Nachweis von in Stuhl und/oder Urin enthaltenen, bakteriellen und/oder viralen und/oder mykotischen Erregern, **dadurch gekennzeichnet**, daß ein Teststreifen (3) mit einer auf spezifische Erreger sensitiven Detektorzone (3a) in einer Windel (1) anbringbar ist, wobei sich die Detektorzone (3a) unterhalb einer flüssigkeitsdurchlässigen Windelmembrane (2) befindet, die auf der körperzugewandten Innenseite der Windel (1) angeordnet ist.
2. Indikatoreinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Detektorzone (3a) zwischen der Windelmembrane (2) und einer darunterliegenden, flüssigkeitsaufnehmenden Saugschicht (5) positioniert ist.
3. Indikatoreinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Windel eine flüssigkeitsdichte Außenschicht (6) aufweist.
4. Indikatoreinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Teststreifen (3) manuell lösbar befestigt ist.
5. Indikatoreinrichtung nach Anspruch 4, dadurch gekennzeichnet, daß der Teststreifen (3) einen Handhabungsabschnitt (3b) aufweist, der in eingesetztem Zustand nach außen über die Windel (1) vorsteht.
6. Indikatoreinrichtung nach Anspruch 5, dadurch gekennzeichnet, daß der Handhabungsabschnitt (3b) auf der Außenseite der Windel (1) abtrennbar befestigt ist.

6

7. Indikatoreinrichtung nach Anspruch 4, dadurch gekennzeichnet, daß die Außenschicht (6) der Windel (1) ein manuell auftrennbares Entnahmefenster für den Teststreifen (3) aufweist.

8. Indikatoreinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Windel (1) als Einweg-Windel ausgebildet ist.

9. Indikatoreinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß die Detektorzone (3a) des Teststreifens (3) sensitiv bezüglich der Erreger gastrointestinaler und/oder Harnwegsinfektionen ist.

10. Indikatoreinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Teststreifen (3) als Einweg-Teststreifen ausgebildet ist.

11. Indikatoreinrichtung nach Anspruch 1, dadurch gekennzeichnet, daß der Teststreifen (3) in einem Schnelltestverfahren auswertbar ist.

12. Verwendung eines Teststreifens mit einer auf bakterielle und/oder virale und/oder mykotische Erreger sensitiven Detektorzone zum diagnostischen Nachweis solcher Erreger im Stuhl, gekennzeichnet dadurch, daß der Teststreifen (3) in dem Bereich einer Windel (1) angebracht ist, der den flüssigen Stuhlbestandteilen ausgesetzt ist.

13. Nachweisverfahren zur diagnostischen Feststellung von in Stuhl und/oder Urin enthaltenen, bakteriellen und/oder viralen und/oder mykotischen Erregern, gekennzeichnet durch die Verfahrensschritte, daß ein Teststreifen (3) mit einer auf spezifische Erreger sensitiven Detektorzone (3a) vorzugsweise in einer Windel (1) angebracht wird, wobei die Detektorzone (3a) unmittelbar unterhalb einer flüssigkeitsdurchlässigen Windelmembrane (2) positioniert wird, und daß nach erfolgter Stuhl- und/oder Urinabgabe der Teststreifen (3) aus der Windel (1) entnommen und in einem Schnelltestverfahren entwickelt wird.

Hierzu 1 Seite(n) Zeichnungen

- Leerseite -

ZEICHNUNGEN SEITE 1

Nummer:
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Offenlegungstag:

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Fig.1

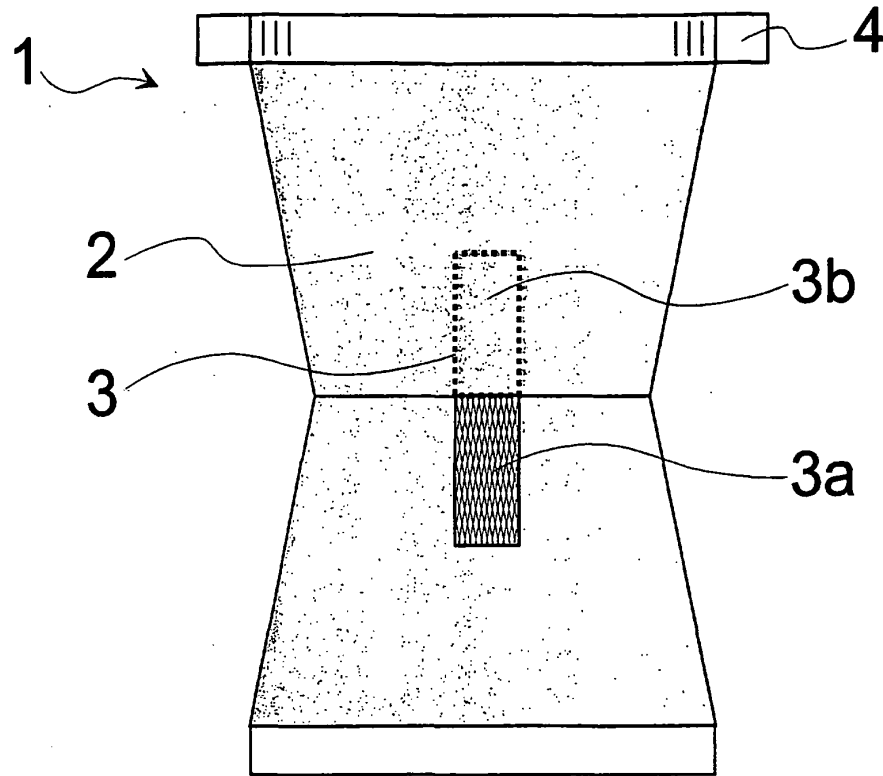
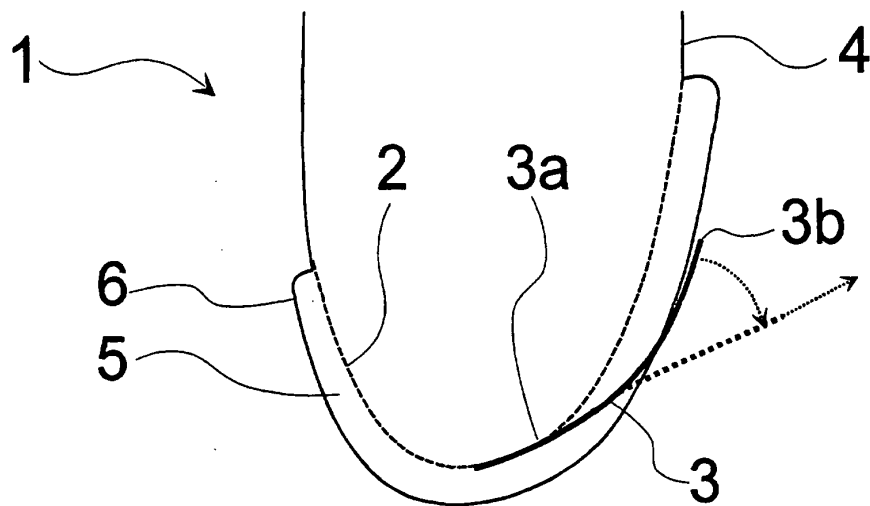


Fig.2



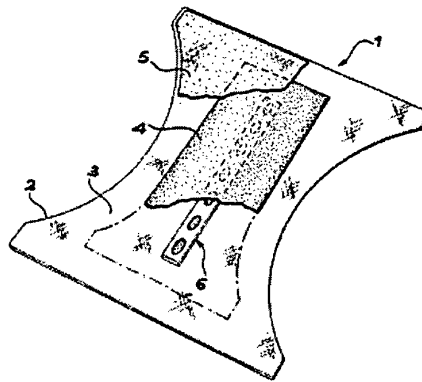
Saturation indicator for absorbent material, e.g. baby's nappy

Publication number: FR2733146
Publication date: 1996-10-25
Inventor:
Applicant: CARRIEL JEAN CLAUDE (FR)
Classification:
- international: A61F13/42; A61F13/42; (IPC1-7): A61F13/42
- European: A61F13/42
Application number: FR19950004592 19950418
Priority number(s): FR19950004592 19950418

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Abstract of FR2733146

The indicator (6) contacts the absorbent layer (4) of a nappy and comprises a perforated plastic sleeve containing a strip of material which changes colour when wet. The outer impermeable layer (2) of the nappy is transparent or translucent, so that the colour of the indicator strip can be seen through it, showing when the baby needs changing. The perforated sleeve can be made as an integral part of the outer layer of the nappy, or it can be stuck to its inner layer by adhesive. The colour-change material can be made from blotting paper.



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①⑨ RÉPUBLIQUE FRANÇAISE
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⑤① Int Cl⁸ : A 61 F 13/42

⑫ **DEMANDE DE BREVET D'INVENTION** **A1**

②② Date de dépôt : 18.04.95.

③⑩ Priorité :

④③ Date de la mise à disposition du public de la
 demande : 25.10.96 Bulletin 96/43.

⑤⑥ Liste des documents cités dans le rapport de
 recherche préliminaire : *Se reporter à la fin du
 présent fascicule.*

⑥① Références à d'autres documents nationaux
 apparentés :

⑦① Demandeur(s) : *CARRIEL JEAN CLAUDE — FR.*

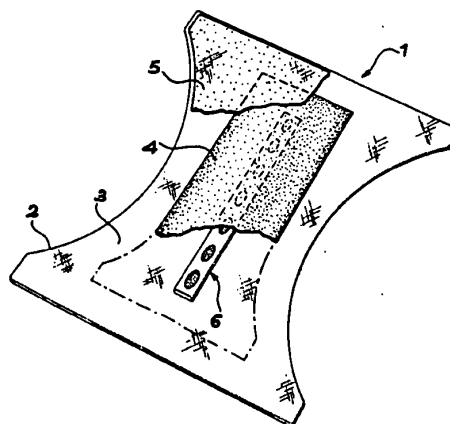
⑦② Inventeur(s) :

⑦③ Titulaire(s) :

⑦④ Mandataire : *SOCIETE DE PROTECTION DES
 INVENTIONS.*

⑤④ **DISPOSITIF INDICATEUR DE LA SATURATION D'UN MILIEU ABSORBANT ET COUCHE-CULOTTE EQUIPEE
 D'UN TEL DISPOSITIF.**

⑤⑦ L'invention concerne un dispositif indicateur de la sa-
 turation d'un milieu absorbant comprenant des moyens
 sensibles à l'humidité ou à un liquide, logés dans une gaine
 perforée placée au contact du milieu absorbant. Ce dispo-
 sitif (6) peut notamment être disposé sur la face interne (3)
 de la feuille externe imperméable (2) d'une couche-culotte
 (1), entre cette feuille externe et la masse absorbante (4)
 de la couche-culotte.



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**DISPOSITIF INDICATEUR DE LA SATURATION
D'UN MILIEU ABSORBANT ET COUCHE-CULOTTE
EQUIPEE D'UN TEL DISPOSITIF**

La présente invention concerne un dispositif
5 indicateur de la saturation d'un milieu absorbant.
Elle concerne également une couche-culotte équipée
d'un tel dispositif.

On utilise fréquemment, pour absorber
l'humidité environnant un élément ou pour absorber
10 ou éponger un liquide mouillant un corps ou matériel,
une masse absorbante placée à proximité ou contre cet
élément, ce corps ou ce matériel. Selon les cas, cette
masse absorbante est destinée à être jetée ou à être
réutilisée après un traitement approprié.

15 Cette technique d'absorption est notamment
utilisée pour confectionner des couches-culottes,
que ce soit pour des bébés ou des personnes énurétiques.

Une couche-culotte comprend une feuille
externe imperméable et une feuille interne en tissu
20 entre lesquelles est disposée une masse absorbante
de cellulose. La feuille interne doit assurer la
transition rapide de l'urine en direction de la masse
absorbante tout en formant un obstacle au retour de
l'urine vers le corps du bébé ou de la personne
25 énurétique.

Une couche-culotte doit en principe être
changée lorsque la masse absorbante est saturée mais
cet état est difficile à connaître par un simple coup
d'oeil sans l'ouvrir, d'autant plus que certains
30 fabricants proposent des feuilles externes imperméables
de très bonne qualité rendant difficile l'appréciation
de l'état de saturation.

Dans le cas des bébés, les personnes qui
s'en occupent peuvent soit les changer à des intervalles
35 de temps réguliers, auquel cas la couche-culotte n'est

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pas systématiquement saturée, soit les changer au motif que le bébé pleure ou semble mal à l'aise, ce qui n'est d'ailleurs pas non plus une preuve évidente que la couche-culotte est saturée.

5 Dans le cas des personnes âgées ou des personnes ayant des difficultés d'expression le problème est similaire, voire plus critique puisque la vérification ou le changement de couche-culotte est plus difficile et plus délicat à effectuer que pour
10 des bébés.

Il en résulte que le changement de couche-culotte peut être effectué trop tard, c'est-à-dire alors que la couche-culotte est saturée depuis un certain temps. Ceci incommode le porteur
15 de la couche-culotte. Plus grave, cette accumulation d'urines et parfois de fèces peut créer des réactions cutanées : rougeurs, démangeaisons, voire même infections.

Le changement de couche-culotte peut au
20 contraire être effectué trop tôt auquel cas cette intervention n'est pas économique.

Des tentatives ont été faites pour remédier à ces problèmes de manière à donner une indication visuelle correspondant à un état de saturation de la
25 couche-culotte.

Le document FR-A-2 092 574 décrit un article à jeter comprenant une feuille support translucide en une matière sensiblement imperméable à l'eau, à laquelle est superposé un tampon absorbant. Un agent
30 indicateur sensible à l'humidité, sous forme de particules finement divisées, est disposé entre la feuille et le tampon dans au moins une zone indicatrice. L'humidité induit un changement de teinte de l'agent indicateur. L'application de l'indicateur sensible
35 à l'humidité peut être étendue à l'ensemble de la face

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du tampon absorbant en contact avec la feuille support translucide. Cette application peut aussi être réalisée en une pluralité de zones indicatrices rectangulaires ou circulaires.

5 Le document FR-A-2 541 872 décrit une couche-culotte comportant une feuille externe imperméable, une feuille interne de tissu non tissé et une masse absorbante de cellulose comprise entre ces deux feuilles. La feuille externe imperméable est
10 suffisamment transparente pour que l'on puisse voir de l'extérieur une ou plusieurs marques imprimées réalisées sur sa face interne au moyen d'encres attaquables et solubles dans l'urine et l'humidité accumulées dans la couche-culotte. La disparition de
15 ces marques imprimées est censée indiquer la saturation de la capacité d'absorption de la couche-culotte.

Les articles décrits dans ces documents ne peuvent cependant pas donner entière satisfaction. En effet, l'indicateur sensible est dans les deux cas
20 en contact direct avec la masse absorbante dont l'objectif est non seulement de contenir l'humidité ou l'urine mais également de les concentrer de préférence vers la feuille externe imperméable afin d'éviter leur reflux vers la feuille interne et la
25 peau. Il en résulte que l'indicateur sensible réagit aux premières émissions liquides au lieu de donner véritablement une information sur l'état de saturation de la couche-culotte.

Dans le cas de l'article décrit par le
30 document FR-A-2 092 574, si les particules de l'indicateur sensible sont réparties sur l'ensemble d'une face du tampon absorbant, on est amené à utiliser une grande quantité d'indicateur pour obtenir un résultat appréciable. Si au contraire, les particules
35 sont réparties selon des zones bien localisées (voir

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les figures 3 à 5 de ce document), on peut s'attendre à avoir une diffusion superficielle de l'indicateur au contact du liquide et donc une atténuation du changement de coloration. D'autre part, que les
5 particules de l'indicateur soient réparties uniformément en surface ou localisées, leur mise en place complique singulièrement le procédé de fabrication d'une couche-culotte.

Dans le cas de l'article décrit par le
10 document FR-A-2 541 872, c'est la disparition de marques imprimées qui est censée indiquer l'état de saturation. Cependant, la disparition d'un indicateur est moins révélatrice que l'apparition d'une marque colorée. A la rigueur, on peut même oublier qu'il y avait des
15 marques imprimées. D'autre part, le procédé de fabrication d'une couche-culotte s'en trouve notablement plus compliqué puisque la feuille externe doit en outre être imprimée sur sa face interne avec un type d'encre différent de l'encre indélébile utilisée pour réaliser
20 les dessins ou motifs ornant habituellement la face externe de la feuille externe.

La présente invention permet de remédier à ces inconvénients en proposant l'utilisation d'un support imprégné de réactif, placé sur la face interne
25 de la feuille externe et mis en contact localement avec la masse absorbante. Ce support peut être mis en place facilement et sans contrainte pour le procédé de fabrication. Le contact localisé entre le support imprégné et la masse absorbante réduit les possibilités
30 de contamination de cette masse absorbante par le réactif. Le réactif utilisé peut être choisi de manière à présenter une coloration nettement décelable en cas de saturation de la masse absorbante.

L'invention a donc pour objet un dispositif
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indicateur de la saturation d'un milieu absorbant
comprenant des moyens sensibles à l'humidité ou à un
liquide destiné à être absorbé par le milieu absorbant,
ces moyens sensibles réagissant à cette humidité ou
5 à ce liquide par changement de coloration et étant
disposés de façon à être visibles, caractérisé en ce
que ces moyens sensibles sont logés dans un gaine
partiellement étanche à ladite humidité ou audit liquide
et disposée de façon que les moyens sensibles soient
10 soumis à l'action de l'adite humidité ou dudit liquide.

Avantageusement, la gaine partiellement
étanche peut présenter au milieu absorbant une surface
comprenant une première partie transmettant l'humidité
ou le liquide et une seconde partie étanche à l'humidité
15 ou au liquide, le rapport de surface de la première
partie à la seconde partie étant tel que les moyens
sensibles changent de coloration dans leur totalité
ou dans une proportion déterminée de leur surface
lorsque la saturation du milieu absorbant est estimée
20 complète. Cette première partie peut être constituée
d'au moins un trou.

D'une manière également avantageuse, la gaine
partiellement étanche peut présenter au milieu absorbant
une surface comprenant une première partie transmettant
25 l'humidité ou le liquide et une seconde partie étanche
à l'humidité ou au liquide, le rapport de surface de
la première partie à la seconde partie et la disposition
de la première partie par rapport à la seconde partie
étant tels que les moyens sensibles changent de
30 coloration dans leur totalité ou dans une proportion
déterminée de leur surface lorsque la saturation du
milieu absorbant est estimée complète. Cette première
partie peut être formée de plusieurs trous.

Les moyens sensibles peuvent être constitués
35 par un support sur lequel est déposée une substance

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réagissant à ladite humidité ou audit liquide. Cette caractéristique présente l'avantage d'être économique. Le support peut en effet être simplement du papier buvard.

5 La gaine peut avantageusement être réalisée en matériau plastique.

 Un autre objet de la présente invention est constitué par une couche-culotte comportant une feuille externe imperméable transparente ou translucide, une
10 feuille interne perméable et un milieu absorbant compris entre les deux feuilles, la couche-culotte comprenant en outre sur la face interne de la feuille externe au moins un dispositif indicateur de la saturation du milieu absorbant tel que défini ci-dessus.

15 La gaine peut faire partie intégrante de la feuille externe et donc être réalisée en même temps. Les moyens sensibles, par exemple une bande de papier buvard imprégné de réactif, peuvent alors être insérés par glissement dans la gaine.

20 La gaine peut aussi être rapportée, par exemple par collage, sur la face interne de la feuille externe.

 L'invention sera mieux comprise et d'autres avantages et particularités apparaîtront à la lecture
25 de la description qui va suivre, donnée à titre d'exemple non limitatif, accompagnée des dessins annexés parmi lesquels :

- la figure 1 est une vue du côté interne d'une couche-culotte selon l'invention,

30 - la figure 2 est une vue d'un dispositif indicateur de saturation selon l'invention.

 A la figure 1, on voit le côté interne d'une couche-culotte 1 dépliée. Cette couche-culotte comprend une feuille externe 2, dont on voit par conséquent
35 la face interne 3, une masse absorbante 4 en cellulose

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représentée partiellement et une feuille interne 5 partiellement enlevée. La masse absorbante 4 a une forme assimilable à un rectangle dont les grands côtés sont disposés parallèlement à l'axe longitudinal de la couche-culotte. De manière classique, la feuille externe 2 est imperméable et est réalisée en plastique.

La couche-culotte 1 est pourvue d'un dispositif indicateur de saturation 6 selon l'invention. Ce dispositif indicateur 6 se présente sous la forme d'un long parallélépipède plat disposé dans l'axe longitudinal de la couche-culotte.

Le dispositif indicateur 6 est représenté isolément à la figure 2. Il comprend une gaine 7 enveloppant un support 8 sur lequel est déposée une substance réagissant à la présence d'urine. Au montage, le support 8 peut être glissé dans la gaine à partir de l'une de ses extrémités laissée ouverte. Cette extrémité peut être ensuite obturée par collage ou scellée. La face supérieure de la gaine, qui vient en contact avec la masse absorbante 4 est pourvue de trous 9 qui mettent en relation le support 8 et la masse absorbante 4.

La face inférieure de la gaine 7 est pourvue d'un adhésif pour sa fixation sur la face interne 3 de la feuille externe 2.

Le support 8 peut être simplement une bande de papier buvard que l'on imbibe d'une substance réactive. A titre d'exemple, on peut utiliser comme substance réactive l'un des produits cités dans le document FR-A-2 092 574. On peut aussi utiliser le vert de bromocrésol à une concentration de 0,1 g pour 100 cm³ d'alcool éthylique à 20°C. Un support en papier buvard, après imprégnation et séchage, devient jaune pâle. Il devient vert bleuté ou bleu foncé au contact de l'urine.

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La face inférieure de la gaine 7 et la partie correspondante de la feuille externe 2 doivent être incolores ou légèrement teintées pour permettre de distinguer le changement de couleur du support imbibé de réactif 8.

La dimension et la répartition des trous peuvent être prévues pour avoir un changement de couleur concernant la totalité ou une partie déterminée du support imbibé lorsque la masse absorbante 4 est estimée saturée. Les valeurs de dimension et de répartition des trous peuvent être obtenues par le calcul ou au cours d'essais à la portée de l'homme du métier.

A titre d'exemple, on peut utiliser une bande de papier buvard de 1 cm de large et un peu moins longue que la longueur de la masse absorbante. La surface totale des trous peut représenter environ le cinquième de la surface que présente la gaine à la masse absorbante. Les trous peuvent être ronds ou rectangulaires et répartis de manière homogène.

Au lieu de venir rapporter une gaine sur la face interne de la feuille externe, la gaine peut être un appendice de la feuille externe et donc être obtenue en même temps qu'elle. Un avantage de ceci est de pourvoir éliminer une paroi entre le support imbibé et la feuille externe, cette feuille externe pouvant constituer la face inférieure de la gaine. Il suffirait donc d'introduire le support imbibé dans la gaine par une fente appropriée que l'on peut ensuite obturer, recouvrir ou sceller.

Il entre dans le cadre de la présente invention de conférer au dispositif indicateur de saturation d'autres formes que celle représentée sur les dessins, ou de lui imposer d'autres emplacements sur la feuille externe. On peut prévoir plusieurs dispositifs indicateurs répartis sur la feuille externe de manière appropriée.

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En fonction de la destination de la
couche-culotte (selon le sexe et l'âge du bébé ou s'il
s'agit d'une personne alitée en permanence par exemple),
l'emplacement et la forme du dispositif indicateur
5 de saturation (ou des dispositifs le cas échéant)
peuvent varier pour obtenir de meilleurs résultats.

La gaine perforée enveloppant le support
imbibé de réactif permet un contact progressif entre
la substance réactive et l'urine recueillie par la
10 masse absorbante. Le changement de coloration obtenu
peut ainsi être proportionnel à la quantité d'urine
émise. Cette caractéristique rend l'invention
particulièrement efficace contrairement aux dispositifs
de l'art antérieur.

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REVENDECATIONS

1. Dispositif indicateur (6) de la saturation d'un milieu absorbant comprenant des moyens sensibles à l'humidité ou à un liquide destiné à être absorbé
5 par le milieu absorbant, ces moyens sensibles réagissant à cette humidité ou à ce liquide par changement de coloration et étant disposés de façon à être visibles, caractérisé en ce que ces moyens sensibles sont logés dans un gaine (7) partiellement étanche à ladite
10 humidité ou audit liquide et disposée de façon que les moyens sensibles soient soumis à l'action de ladite humidité ou dudit liquide.

2. Dispositif selon la revendication 1, caractérisé en ce que la gaine (7) partiellement étanche
15 présente au milieu absorbant une surface comprenant une première partie transmettant l'humidité ou le liquide et une seconde partie étanche à l'humidité ou au liquide, le rapport de surface de la première partie à la seconde partie étant tel que les moyens
20 sensibles changent de coloration dans leur totalité ou dans une proportion déterminée de leur surface lorsque la saturation du milieu absorbant est estimée complète.

3. Dispositif selon la revendication 2,
25 caractérisé en ce que la première partie transmettant l'humidité ou le liquide est formée d'au moins un trou (9).

4. Dispositif selon la revendication 1, caractérisé en ce que la gaine (7) partiellement étanche
30 présente au milieu absorbant une surface comprenant une première partie transmettant l'humidité ou le liquide et une seconde partie étanche à l'humidité ou au liquide, le rapport de surface de la première partie à la seconde partie et la disposition de la
35 première partie par rapport à la seconde partie étant

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tels que les moyens sensibles changent de coloration dans leur totalité ou dans une proportion déterminée de leur surface lorsque la saturation du milieu absorbant est estimée complète.

5 5. Dispositif selon la revendication 4, caractérisé en ce que la première partie transmettant l'humidité ou le liquide est formée de plusieurs trous (9).

10 6. Dispositif selon l'une quelconque des revendications 1 à 5, caractérisé en ce que les moyens sensibles sont constitués par un support (8) sur lequel est déposée une substance réagissant à ladite humidité ou audit liquide.

15 7. Dispositif selon la revendication 6, caractérisé en ce que ledit support (8) est constitué de papier buvard.

 8. Dispositif selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la gaine (7) est réalisée en matériau plastique.

20 9. Couche-culotte (1) comportant une feuille externe imperméable (2) transparente ou translucide, une feuille interne perméable (5) et un milieu absorbant (4) compris entre les deux feuilles, la couche-culotte comprenant en outre, sur la face interne (3) de la
25 feuille externe (2) au moins un dispositif indicateur (6) de la saturation du milieu absorbant selon l'une quelconque des revendications 1 à 8.

30 10. Couche-culotte selon la revendication 9, caractérisée en ce que la gaine (7) fait partie intégrante de la feuille externe (2).

 11. Couche-culotte selon la revendication 9, caractérisée en ce que la gaine (7) est rapportée sur la face interne de la feuille externe (2).

35 12. Couche-culotte selon la revendication 11, caractérisée en ce que la gaine (7) est rapportée sur ladite face interne (3) par collage.

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13. Couche-culotte selon la revendication 12, caractérisée en ce que la gaine (7) comporte une face adhérente permettant son collage sur ladite face interne (3).

5 14. Couche-culotte selon l'une quelconque des revendications 9 à 13, caractérisée en ce que le dispositif indicateur de saturation (6) a la forme d'une bande disposée dans l'axe longitudinal de la couche-culotte (1).

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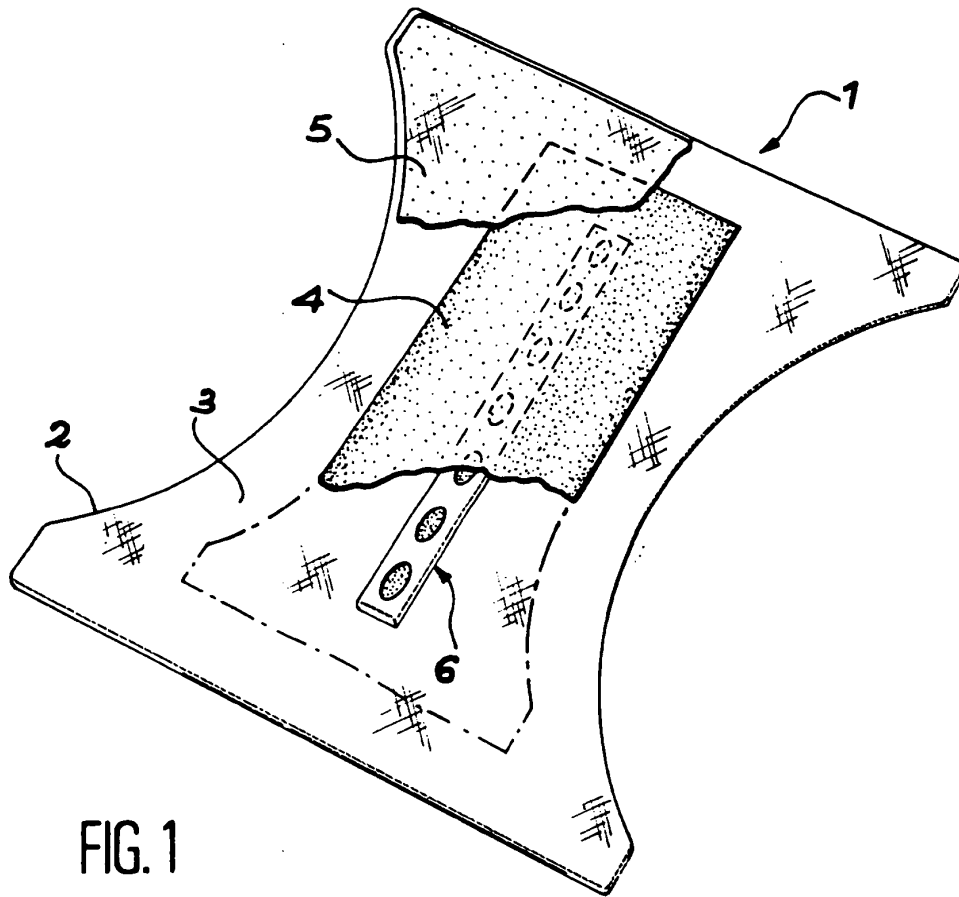


FIG. 1

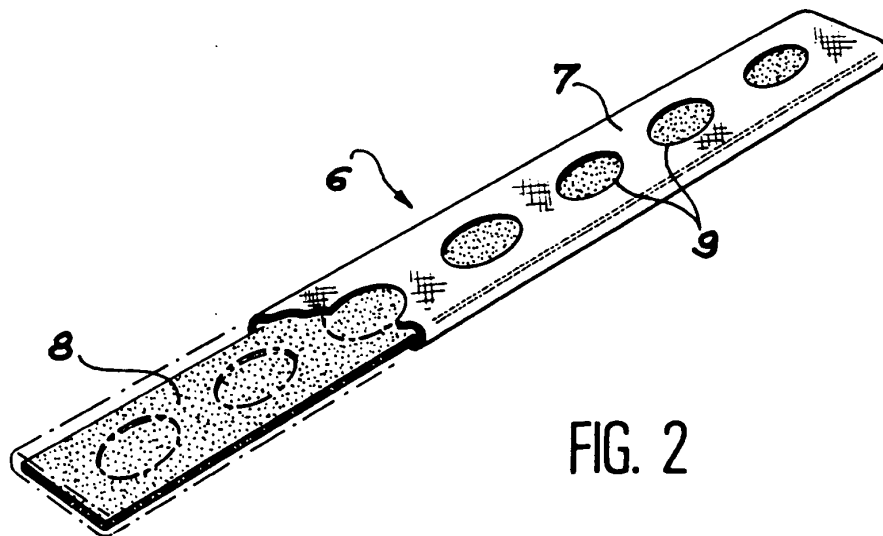


FIG. 2

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2733146

INSTITUT NATIONAL
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RAPPORT DE RECHERCHE
PRELIMINAIRE
établi sur la base des dernières revendications
déposées avant le commencement de la recherche

N° d'enregistrement
nationalFA 513479
FR 9504592

DOCUMENTS CONSIDERES COMME PERTINENTS		Revendications concernées de la demande examinée
Catégorie	Citation du document avec indication, en cas de besoin, des parties pertinentes	
X	US-A-4 507 121 (LEUNG) * le document en entier * ---	1-4, 6, 8-10
X	DE-A-20 31 104 (SIEVERS) * page 5, alinéa 2 - page 7, alinéa 3 * ---	1, 2, 4, 6, 8, 9, 11-14
X	WO-A-94 10958 (MITCHELL) * abrégé; figures * ----	1, 2, 4, 9, 11, 12, 14
A	US-A-2 681 032 (SHAW) * le document en entier * -----	3, 5, 7
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WETNESS MONITORING SYSTEM

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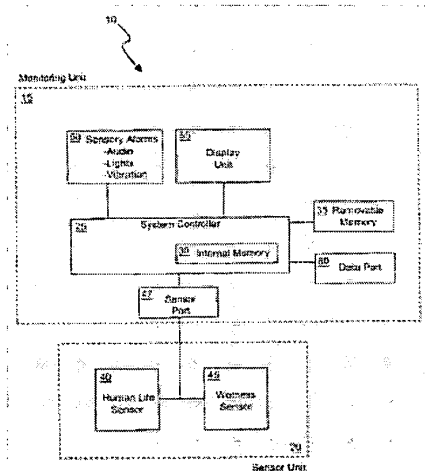
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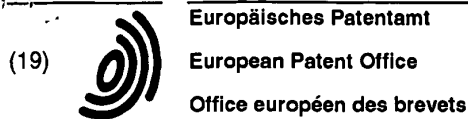
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Abstract of corresponding document: **WO2004049969**

A personal care monitoring system (10) is disclosed. In accordance with one embodiment, the monitoring system may include a wetness sensor (45) configured to detect a wetness event occurring within an associated diaper (80), and a human life sensor (40) configured to detect presence of human life relative to the associated diaper. A monitoring unit (15) having a system controller (25) in communication with the wetness and human life sensors may be utilized in such a manner that the system controller monitors the wetness and human life sensors and generates data associated with detected wetness events and presence of human life relative to the associated diaper.



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(54) **System for detection of electrically conductive fluids**

(57) Apparatus for detecting the presence of electrically conductive fluids, including urine and other body fluids such as exudates from wounds, includes spaced-apart electrodes (44, 46, 96, 98) covered by absorbent material (58, 106, 108, 126, 128), together with a housing (30, 86, 154) containing a signaling device (32, 152, 172, 175) which produces a palpable vibration, a sound, a light, or a radio signal when fluid in the absorbent material provides a conductive path between the electrodes. Spring contacts (50, 138, 146) on the housing provide reliable connections with the electrodes and also serve to attach the housing of the signaling device (32) to structure (12, 78) supporting the adsorbent material, and may also be used to attach the adsorbent material to the housing in embodiments where the housing is otherwise supported. Encoded signals from many such sensors (160, 170) can be identifiably related to and recorded so as to be machine-retrievable together with other patient data and analyzed statistically by a computer (178, 183).

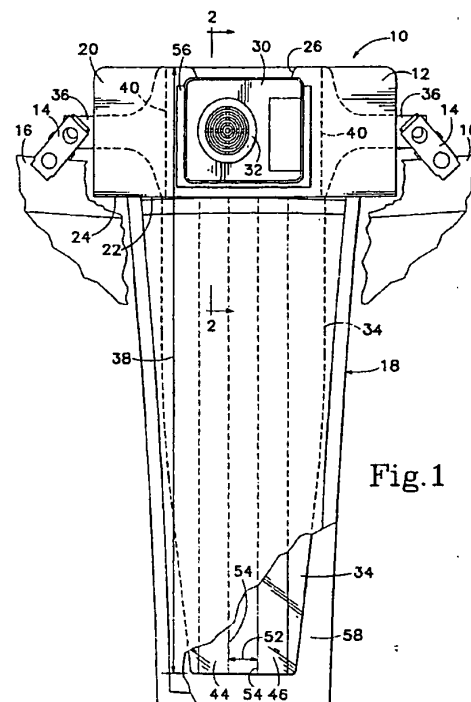


Fig.1

EP 1 063 624 A1

Description**Background of the Invention**

[0001] The present invention relates to detection of electrically conductive fluids, and in particular to detecting and signaling the release of bodily fluids from human beings or animals.

[0002] For many years the objective of electrically detecting and indicating the presence of body fluids or other electrically conductive liquids has been pursued. Detecting such fluids often has involved using a pair of electrodes connected with a voltage source and a detector circuit intended to turn on an audible alarm when a gap between the electrodes is bridged by an electrically conductive fluid.

[0003] Devices for detecting body fluids are desired particularly for assisting in the prevention of diaper rash, for potty training of infants, and in curing enuretic youngsters, as well as for detecting the leakage of blood or other fluids after surgery and invasive diagnostic procedures. Such devices are also desired to monitor and record urinary incontinence and to facilitate better care for pressure sores in chronically bedridden persons.

[0004] Such devices could also be useful for detecting leaks in domestic hot water heaters or other liquid storage devices.

[0005] Previously available devices for use to detect human body fluids have many disadvantages. For example, some prior art devices are too bulky and uncomfortable for use in the groin area for monitoring urinary incontinence. Some prior art devices use cumbersome and unsafe long electric wires to interconnect the necessary component parts.

[0006] Other drawbacks of previously available devices include sensors which are too large or too small, are not shaped properly, or are made of materials which are not compatible with the human body or other intended environment. In particular, prior art devices have not satisfactorily provided for early detection of small amounts of body fluids. Also, many prior art devices are too expensive to manufacture economically or are impractical to use.

[0007] What is desired, then, is a system including an improved sensor and an associated alarm system for reliably and consistently detecting and signaling the presence of electrically conductive fluids under all conditions of use, without false alarms. Such a sensor should be of small size, comfortable to use, easy to maintain, clean, and prepare for reuse, self-powered, and portable. Preferably, a system incorporating such a sensor should have the ability to provide signals to remote monitors for collection and analysis of data, and should be simple to use.

Summary of the Invention

[0008] The present invention provides improved ap-

paratus to overcome the aforementioned shortcomings of the prior art and, in particular, provides an improved, simple, and versatile device for signaling the presence of electrically conductive fluids, such as urine, wound exudate, feces, blood, and water, and also provides a disposable absorbent pad for use in detecting such electrically conductive fluids.

[0009] An important feature of one embodiment of the present invention is the use of comfortable, soft, non-absorbent material to support an absorbent sensor and a housing for a signaling device including an electrical circuit which form parts of the device.

[0010] In one embodiment of the invention a fluid-absorbent sensing pad has two apart-spaced electrodes, included in the structure of the absorbent pad and available to be connected electrically to the signaling device.

[0011] One embodiment of the invention provides a sensing pad whose design and shape provide comfortable positioning and detection of even very small amounts of body fluids for either male or female users.

[0012] It is a feature of one embodiment of the present invention that the fluid-detecting electrode system is compatible with different signaling devices that provide vibratory, audible, visible, or wireless signals.

[0013] One embodiment of the invention provides a disposable fluid-absorbent sensor material which can be cut to a desired length from a continuous roll.

[0014] One embodiment of the invention includes a radio transmitter and an encoding device for sending a signal which is identifiably encoded for reception and interpretation by a remotely located receiver, which may be portable.

[0015] In one embodiment of the invention encoded information may include identification of the source of the encoded signal, while equipment associated with the receiver can record the received signal identification information as well as time of receiving a signal, and can then compute elapsed time since an earlier signal was received, and other information.

[0016] One embodiment of the invention includes the use of an FM radio transmitter which transmits on the commercial FM broadcast frequency band. Signals from such an FM transmitter can be received by conventional domestic radio receivers, enabling most users to have more than one remote receiver.

[0017] The foregoing and other objectives, features, and advantages of the invention will be more readily understood upon consideration of the following detailed description of the invention, taken in conjunction with the accompanying drawings.

Brief Description of the Drawings

[0018] FIG. 1 is a front view of a bed-wetting detection device embodying the present invention.

[0019] FIG. 2 is a sectional view of the device shown in FIG. 1, taken along line 2-2.

[0020] FIG. 3 is a rear view of the carrier assembly

portion of the bed-wetting detection device shown in FIG. 1, together with a portion of an absorbent sensor pad and a fastener for attaching the pad to the carrier assembly.

[0021] FIG. 4 is a perspective view of a housing for electronic components of a signaling device which is a part of the apparatus shown in FIG. 1.

[0022] FIG. 5 is a perspective view, taken from the opposite side, of the housing for electrical components shown in FIG. 4.

[0023] FIG. 6 is an electronic circuit diagram for an audio-output alarm which is part of a signaling device for use in the apparatus shown in FIG. 1.

[0024] FIG. 7 is a plan view of an apparatus similar to that shown in FIG. 1 and including a belt for attachment of the device to a person.

[0025] FIG. 8 is a perspective view of a device for detecting conductive fluid such as body fluids which is an alternative embodiment of the invention.

[0026] FIG. 9 is a perspective view of a roll of absorbent sensor material including absorbent layers and electrodes, according to the invention, useful as a disposable sensing pad material in detecting electrically conductive fluids in accordance with the present invention.

[0027] FIG. 10 is a sectional view, taken along line 10-10, showing the structure of the material shown in FIG. 9.

[0028] FIG. 11 is a side elevational view of the housing shown in FIG. 8, together with a disposable sensing pad.

[0029] FIG. 12 is a view similar to FIG. 11, showing the spring fingers held in a contact-releasing position by a cam.

[0030] FIG. 13 is a side elevational view of a detail of a housing similar to that shown in FIGS. 8, 11 and 12, and equipped with spring fingers which include somewhat different electrical contacts.

[0031] FIG. 14 is a view of a contact shown in FIG. 13, taken in the direction indicated by line 14-14.

[0032] FIG. 15 is a partially cut-away view of a housing for electronic circuitry for providing a quiet signal which can be felt by the wearer of a device according to the present invention, including a clip for attachment of the housing to a person's clothing.

[0033] FIG. 16 is an electronic circuit diagram illustrating a circuit for use in connection with the vibrator signaling device shown in FIG. 15.

[0034] FIG. 17 is a simplified view of a system including a radio transmitter and receiver in combination with a sensor according to the present invention for detecting the presence of electrically conductive fluids.

[0035] FIG. 18 is a view similar to FIG. 17, showing the use of a receiver in accordance with the present invention to provide a visible indication of a signal from a sensing device.

[0036] FIG. 19 is an electronic circuit diagram for a portion of a signaling device for use in accordance with the present invention, including a signal repeat timer.

[0037] FIG. 20 is a block diagram of a system accord-

ing to the present invention including several body fluid detection devices each including a wireless signaling device.

[0038] FIG. 21 is a view of a system monitoring unit and several sensing devices of a system according to the present invention.

Detailed Description of the Preferred Embodiments

[0039] Referring now to the drawings which form a part of the disclosure herein, and with particular reference to FIGS. 1-6, an apparatus for detecting the presence of electrically conductive fluids, in the form of a bed wetting detector 10, includes a sensor carrier assembly 12 having a flat, generally rectangular configuration adapted to fit, for example, against the front of a wearer's night clothes as support for the detector 10. The carrier assembly 12 includes a pair of alligator clips 14, one attached at each end, as one way to attach the carrier assembly 12 to a person's clothing, such as the elastic waistband 16 of a pair of underpants, to keep it in a desired location in which a sensor portion 18 is best positioned to receive and absorb urine when the person wearing the device first begins to urinate while sleeping.

[0040] The carrier assembly 12 is constructed of a sheet 20 of closed-cell polymeric foam material which may be 3 mm thick, for example, folded along a central slit 22 to define a horizontal bottom 24 of the carrier assembly. A recess 26 is defined on the front part of the carrier assembly 12 by a cutout in the top margin 28 of the folded sheet 20, providing a convenient location for attachment of a housing 30 containing electrical circuit components including a signaling device 32.

[0041] The sensor portion 18 of the device 10 is reusable and includes an electrode-carrying member 34 in the form of a backing layer of sheet plastic material such as polyvinylchloride 0.50 mm thick having a pair of opposite longitudinal margins, an upper portion of each of which extends laterally defining tabs 36 to which the alligator clips 14 are attached. The electrode-carrying member 34 may, for example, have a length 38, of about 23 cm overall, with about 18.7 cm depending downward below the central slit 22 in the closed-cell foam material of the sheet 20. The depending portion of the electrode-carrying member in a preferred embodiment of the invention is 7 cm wide over approximately its upper half, its lower half tapering to a width of approximately 4.5 cm at its lower end.

[0042] A rectangular piece 40 of flexible plastic material such as polyvinylchloride 0.25 mm thick extends lengthwise between the opposite halves of the folded sheet 20 of closed-cell foam material and is attached along its vertical ends to the rear side of the upper portion of the electrode-carrying member 34. The inner surfaces of the sheet 20 of closed-cell foam are attached to the flexible plastic material of the piece and of the electrode-carrying member by an adhesive, such as ADCHEM 5008B, available from Adchem Corporation

of Westbury, New York. A space 42, open at its top and bottom is thus defined between the piece 40 of flexible plastic material and the upper portion of the electrode-carrying member 34.

[0043] Two parallel, flexible electrodes 44, 46 are attached to the electrode-carrying member 34 on its rear side, that is, the side facing toward the body of the user of the device. The electrodes 44, 46 are thus exposed, spaced apart from and parallel with each other, within the space 42 defined between the piece 40 of flexible plastic material and the electrode-carrying member 34.

[0044] The housing 30 is attached to the carrier assembly 12 by a pair of spring fingers 48 of resilient sheet metal, each of which is electrically connected appropriately to the electronic circuit components contained within the housing 30, as shown in FIG. 6, and each of which also includes a contact portion 50. The resilient spring fingers 48 attached to the housing bring each of the contact portions 50 into mechanical and electrical contact with a respective one of the electrodes 44, 46 within the space 42 defined between the flexible plastic 40 and the electrode-carrying member 34. Preferably, each of the fingers 48 has an upturned tip, to facilitate sliding the housing into position with the fingers 48 in the space 42, with each contact portion 50 contacting a respective one of the electrodes 44, 46.

[0045] Each of the electrodes 44, 46 is a strip of conductive flexible polyimide material impregnated with carbon black, such as that available from DuPont Electronics of Wilmington, Delaware, and known as KAPTON 400XC250, which has a suitably low resistivity of 250 ohms/sq. Each of the electrodes 44, 46 is approximately 1.3 cm wide, and a spacing 52 of approximately 1.1 cm is provided between the medial margins 54 of the two electrodes.

[0046] Preferably, an additional piece 56 of flexible plastic is attached by an adhesive to the front face of the carrier assembly to protect the closed-cell foam material of the sheet 20 from possible abrasion by the surface of the housing 30, and to facilitate removal and replacement of the housing 30 from and onto the carrier assembly 12.

[0047] An absorbent sleeve 58 fits around the electrode-carrying member 34 and the electrodes 44, 46, fitting snugly against the bottom 24 of the carrier assembly 12, adjacent the central slit 22. A flap 60 extending upward on the rear side of the sleeve 58 carries a small patch 62 of the hook-bearing material of a hook-and-loop fastener system such as that known by the trademark Velcro®, while a patch 64 of the loop-bearing material of the fastener system is attached, as by an adhesive, to the rear surface of the sheet 20 of closed-cell foam material of the carrier assembly 12, so that mating the two fastener materials 62, 64 holds the sleeve 58 appropriately in position covering the depending portions of electrode-carrying member 34 and the electrodes 44, 46.

[0048] The sleeve 58 is made of an absorbent mate-

rial which is preferably washable, such as a central layer 66 of a batting of polyester fibers, covered on opposite faces by layers 68 of thin, fluid-absorbent cloth such as a cotton-polyester blend, which may be quilted, with front and rear panels of the resultant three-layer fabric being sewn together along their respective longitudinal margins and bottom margin. The entire sensor portion 18, including the sleeve 58 and the electrode-carrying member 34, is flexible but not too bulky to be worn comfortably within a user's underwear.

[0049] Referring to FIG. 6, the bedwetting detector 10 includes an audio alarm which may be contained as a signaling device 32 within the housing 30. An electronic switch 70, such as a Harris H11 A10 photon-coupled current threshold switch, in which a solid-state gallium arsenide infrared-emitting diode is coupled with a silicon phototransistor in a dual in-line package, is connected to provide power from a battery 72 to an audio transducer 74 which may, for example, be a Series A1612 electronic solid-state audio indicator unit available from Projects Unlimited, Inc. of Dayton, Ohio, capable of providing 90 dba sound pressure at a frequency of about 400 Hz.

[0050] When a circuit is completed through an electrically-conductive fluid absorbed in the sleeve 58 in a location interconnecting the electrodes 44 and 46, the current through the electrically-conductive fluid is sufficient to turn on the electronic switch 70, providing a current path from the battery 72 through the audio transducer 74, so long as the battery 72 lasts and the circuit remains intact through the sensor portion 18 of the device. Thus, when moisture, such as a sufficient quantity of urine, completes the circuit the audio transducer 74 will produce enough noise to waken the person wearing the device 10, usually a small child, to enable the child to stop urinating and to learn to awaken before wetting the bed. The noise of the transducer 74 can be stopped by simply removing the spring fingers 48 of the housing 30 from contact with the electrodes 44, 46 within the carrier assembly 12.

[0051] Once the sleeve 58 has been made wet, it can be removed, permitting the carrier assembly 12, the electrode-carrying member 34, and the electrodes 44, 46 of the sensor portion 18 of the device, and the exterior of the housing 30, to be wiped dry. Thereafter, the sleeve 58 can be replaced with a dry one and the housing 30 can be replaced on the carrier assembly 12, allowing the bedwetting detector 10 to continue to monitor the wearer.

[0052] Referring to FIG. 7, as an alternative embodiment of the apparatus shown in FIGS. 1-6, a carrier assembly 76 may include, instead of the pair of alligator clips 14 at the ends of the carrier assembly 12, a belt 78 of closed-cell foam material similar to that of the sheet 20 of the body of the carrier assembly 12. The belt 78 is equipped with mating patches 80, 82 of hook-and-loop fastener material, and excess length of the belt can be trimmed easily, so that the device can be used with

people of different sizes.

[0053] Referring next to FIGS. 8-12, a body fluid detecting device 84 which is another embodiment of the invention includes a housing 86 for electronic circuitry similar to the housing 30 previously described. It includes an alligator clip 88 attached to the housing, as by a looped strip 90 of flexible plastic material engaged movably through an opening defined by a small strip 92 of plastic material fastened to the housing.

[0054] Instead of the carrier assembly 12 and the associated reusable sensor portion 18, however, the body fluid sensing device 84 shown in FIGS. 8-12 utilizes a disposable sensing pad 94 of absorbent sensor material 95 which includes a pair of electrodes 96, 98. The absorbent sensor material of the disposable sensing pad 94, as shown in FIGS. 9 and 10, has the form of an elongate strip and may be provided in the form of a roll of such material 95 which can be cut to a desired or required length. For example, for use to detect urinary incontinence, a strip of the absorbent sensor material 95 may be cut approximately the same length, in the direction indicated by the arrow 100, as the length of the electrode-carrying member 34 of the reusable sensor 18 described previously, or to a shorter or longer length, depending upon the size of the person using the device.

[0055] Two strips 102 of an adhesive material, normally covered by an easily removable protective paper tape 104, are available on one face of the disposable sensing pad 94, to be used to attach the disposable sensing pad 94 to a person's clothing. Where the device is used to detect seepage from a wound, the adhesive material may be used to attach the absorbent sensor material 95 to person's skin, instead, or to a portion of a bandage, as appropriate. An adhesive material such as that available in the form of a spirally rolled strip of adhesive and a protective paper layer from the Minnesota Mining and Manufacturing Company of Minneapolis, Minnesota, as its No. 924 adhesive is suitable, although an adhesive applied in fluid form and then covered with the protective paper tape 104 during the process of manufacture of the absorbent sensor material 95 would also be suitable.

[0056] The absorbent sensor material 95 of the disposable sensing pad 94 is of multi-layered construction, including a pair of inner layers 106, 108 of a continuous, absorbent soft paper or similar material having a width 110 of about 4.5 cm. The pair of flexible electrodes 96, 98 may be ribbon-like strips of polyester plastic provided with a conductive metallic coating, such as aluminum, on each face, and are attached by layers 112 of an adhesive to the sheet 108 of paper, with one metallized face of each electrode facing away from the sheet 108. The closer, or medial, longitudinal margins 114 of the electrodes are spaced apart from one another by, a distance 116 of, for example, 1.2 cm, and each electrode has a width 118 of 1.2 cm, leaving three to four tenths of a centimeter of the width 110 of the paper clear alongside the outer or lateral longitudinal margin 120 of each

electrode.

[0057] The other sheet 106 of the absorbent soft paper overlies the sheet 108 to which the electrodes 96, 98 are adhesively attached, and the two sheets 106, 108 of absorbent paper are attached to each other by strips 122 of adhesive material along their longitudinal margins, and by adhesive material, preferably in the form of a continuous strip 124, located between the two electrodes 96, 98 to prevent them from being pushed into contact with each other as a result of the disposable sensing pad 94 bending to conform to a person's body or clothing during use of the device.

[0058] On each side of the disposable sensing pad 94 an outer layer 126 or 128 of flexible fluid-conducting absorbent material overlies the inner layers 106, 108. The outer layers 126, 128 are attached to each other and to the margins of the inner layer of material, as by adhesive material 130 interconnecting the longitudinally-extending lateral margins 132 of the outer layers with each other and also attaching the outer layer 128 to the inner layer 108, to which the electrodes 96, 98 are adhesively attached. Instead of the adhesive materials 112, 122, 124 and 130, ultrasonic welding may be used to bond together the inner and outer layers 106, 108, 126 and 128 if a weldable bonding agent, such as latex, is included in the materials of the inner or outer layers.

[0059] Each electrode 96, 98 is exposed within a respective tube 134 formed by the opposing surfaces of the inner layers 106, 108 of absorbent soft material. The spring fingers 136 on the outside of the housing 86, each electrically connected appropriately with the electrical components contained within the housing, fit within the tubes 134. The contacts 138 located on the spring fingers 136 thus make electrical contact with the electrodes 96, 98, while the electrodes 96, 98 are kept separate from each other by the bonded-together portions of the inner layers 106, 108.

[0060] The inner layers 106, 108 may, for example, be of a paper product available from Fort Howard Paper Company of Green Bay, Wisconsin as its grade 835 dry form 8-ply lightweight fabric made of bleached pulp. The outer layers 126, 128 may be of a rayon apertured fabric, print bonded with a rope pattern, and available from Fort Howard Paper Company of Green Bay, Wisconsin, as its grade 920 Carded™ material. The material of the outer layers 126, 128 has a lower absorbent capacity but a higher wet tensile strength than the material of the inner layers 106, 108, so that the outer layers provide strength to the disposable sensing pad 94 and allow moisture to pass quickly to the inner layers 106, 108 to be absorbed and brought into contact with the electrodes 96, 98 to complete an electrical path between the electrodes.

[0061] As shown in FIGS. 8, 11 and 12, the spring fingers 136 include down-turned tips as the contacts 138, to provide electrical contact with the electrodes of the absorbent sensor material 95 of the disposable sensing pad 94. The spring fingers each include a zigzag bend,

and the housing 86 includes a raised ridge 140 defining a support for a cam 142 which can be rotated toward the zigzag bend by a lever 144 to raise the contacts 138 away from the housing 86 to permit the ends of the spring fingers 136 to be inserted into the tubes 134 of the disposable sensing pad 94. When the lever 144 is returned to a position parallel with the outer surface of the housing 86 the contacts are urged against and into electrical contact with the electrodes 96, 98 by elastic spring tension in the spring fingers 136.

[0062] As shown in FIGS. 13 and 14, a spring finger 136' includes a multi-tined contact 146 in place of the down-turned contacts 138 of the spring fingers 136 just previously described. Each tine 148 has a length of, for example, about 0.06 cm, long enough to extend through the outer layer 126 and inner layer 106 of the disposable absorbent sensor material 95 to make electrical contact with the electrodes without having to be inserted within the tubes. This construction permits the absorbent sensor material of the disposable sensing pad to be used to present the adhesive 102 facing in a desired direction with respect to the housing 86, to attach the sensing pad 94 either to a patient's undergarment or to a patient's skin, depending upon the application for which the body fluid detecting device 80 is being used. Alternatively, the tines, electrically connected, could be provided on the housing 86 with the spring fingers 136 pressing the electrodes into contact with the tines.

[0063] Certain people, because of medical conditions, are unable to detect normally and reliably when uncontrollable urination is about to begin. In some of such people, however, a small amount of urine, great enough to be detected by a sensing device according to the invention, leaks from the person early enough for the person, if aware of such leakage, to proceed to a toilet to complete voiding the bladder. Such persons can utilize a body fluid sensing device 150 including a vibrator 152 as its signaling device as shown in FIGS. 15 and 16. The vibrator 152 is contained within a housing 154 similar to the housing 86, and can be felt by the wearer, allowing the person wearing the device to proceed to a restroom soon enough to avoid embarrassment by wet clothing. The device 150 itself does not cause embarrassment, however, because its signal is inaudible to nearby people. This permits the person with such a medical problem to live in a substantially normal way, without having to be catheterized or to wear diapers. A suitable vibrator circuit, shown in FIG. 16, includes a TLC 555 integrated circuit available from Tandy Corporation, of Dallas, Texas, which, when connected as shown, latches in a mode providing power to the vibrator 152 once conductivity is established, even briefly, between the spring fingers, as by urine providing a conductive path between electrodes 96, 98 of a disposable sensing pad 94 connected to the contacts 138 of the spring fingers 136 of the housing 154. A suitable vibrator 152 is a vibration pager Model 7CE-1701 WL-00, available from Namiki Precision Jewel Co., Ltd., of Rochelle

Park, New Jersey, which includes a small coreless DC motor and an eccentrically weighted shaft.

[0064] A reusable sensor 18 or a disposable sensor 94 according to the present invention may be used in a system containing one or more of the sensing devices, each equipped with a small, low-powered radio transmitter and one or more receivers and display devices, to monitor, for example, infants, invalids, or nursing home or hospital patients suffering from, among other things, urinary incontinence, pressure sores, surgical wounds, and other problems.

[0065] For example, as shown in FIG. 17, in one basic form of such a system, a transmitter included in body fluid detecting device 160 connected with a sensing pad 94 (or with a reusable sensor 18) transmits at very low power on a frequency within the commercially used FM broadcast band. When an electrically conductive fluid completes the electrical path between electrodes of the sensing pad 94 the transmitter begins to transmit, continuing to transmit a signal until an FM receiver in the close vicinity, as within the same house, for example, alerts a person who can disconnect the device from the electrodes of the sensing pad 94, or until the battery powering the transmitter is exhausted. Preferably, the transmitting frequency is variable to avoid local commercial broadcast frequencies. A timing circuit could be connected to the transmitter (as in the circuit shown in FIG. 19) to limit battery drain.

[0066] A receiving device for use with such a transmitter for a single patient situation may simply be an ordinary household FM receiver 162, so that a caregiver could keep several receivers tuned, in different locations in the house, to receive a signal indicating that attention to the patient is required, or may carry a small portable FM receiver tuned to provide the signal no matter where the responsible person moves within the transmitting range of the device.

[0067] Another receiver device, as shown in FIG. 18, may be a special-purpose receiver 164 including an audible signaling device 166 or visible signaling device 168. A latch circuit is included to turn on the signaling device and keep it activated until turned off or reset by the responsible person.

[0068] A body fluid detecting device 170 which is another embodiment of the invention incorporates a circuit as shown in FIG. 19, and controls a transmitter 172 to provide an FM radio signal which is transmitted for only a limited time, for example one second. The transmitter 172 is reactivated periodically to send another such transmission, with a delay between transmissions which is established by the value of the resistor R_T . For example, when R_T is 10 megohms, the delay is two minutes, and when R_T is 20 megohms the delay is four minutes. (If a first encoded signal transmission is not received by the receiver 164, the next or a subsequent transmission is received by the special purpose receiver 164 and the signaling device 166 is activated and latched "on.") The included transmitter 172 is accompanied by a digital en-

coding device which uniquely identifies the transmitter of the device 170. A transmitter test switch 174 and an indicator lamp 175 which are also provided.

[0069] Where there are multiple patients to be monitored, as in a hospital or nursing home, a central receiving device may be used with several sensing devices 170. Referring now to FIGS. 20 and 21, the nurses' station 176 includes an internal computer 178 and an RS-232 interface 180 through which inputs and outputs to and from an external computer 183 may be directed. The station 176 includes a printer 182 on which the identity of each transmitter 172 of a sensing device 170 and the time of transmission of an incident message signal (indicating a circuit completed through sensor electrodes) or a reset message (indicating use of the transmitter test switch 174) initiates a transmission which is received by the antenna 184. The antenna 184 may be more or less efficient, depending on the needs imposed by the size of the building in which the system is used. An alarm circuit 186 responsive to signals from the computer 178 provides an audio alarm signal 188 and illuminates an indicator lamp 190 to show that a signal has been received. Control circuits 194 connected to the printer-computer interface allow a programming circuit 196 to assign identification of patients to transmitters, each of which has its own unique encoded identification signal which is transmitted as a part of the transmitter protocol each time the transmitter of a body fluid sensing device such as the device 170 is activated. A visual numerical display 198 provides an identifying display of the origin of the latest received transmission.

[0070] A receiver-decoder 200 receives each transmission and passes on the significant portion of the encoded identification signal to be processed through the control circuit 194 into the internal computer 178. These elements are included in a work station receiver available from Linear Corporation of Carlsbad, California as its Linear Model AC-680 receiver, which operates in conjunction with and in response to Linear Model ACT-1/318 transmitters, each enclosed in an individual housing connected to a respective sensor such as an appropriate length of the disposable absorbent sensor material 95, or an appropriately-shaped electrode-carrying member 34 provided with a pair of electrodes 44, 46 and a corresponding sleeve 58 such as those included in the bed-wetting detection device 10 described previously, or modified in size and shape to be appropriate for sensing body fluids exuded from surgical wounds and the like or body discharges from animals, where the device is used in a veterinary application.

[0071] Data accumulated in the internal computer 178 may be transmitted through the RS-232 interface 180 to the external computer 183 for assembly and calculation of statistical data, filing and retrieval, and correlation with other data concerning individual patients or groups of patients. In particular, computer-recorded photographs and medical histories of patients may be stored in a database for retrieval to evaluate patient progress

and efficiency of patient care and caretaker response to body fluid loss as shown by time of receipt of incident messages and reset messages.

[0072] The terms and expressions which have been employed in the foregoing specification are used therein as terms of description and not of limitation, and there is no intention, in the use of such terms and expressions, of excluding equivalents of the features shown and described or portions thereof, it being recognized that the scope of the invention is defined and limited only by the claims which follow.

Claims

1. A sensing pad for use in detecting the presence of electrically conductive fluids, the sensing pad comprising:

(a) a first layer (108), of a flexible sheet material;

(b) a pair of elongate flexible electrodes (96, 98) extending generally parallel with and spaced apart from each other and attached to said first layer (108), each of said electrodes having a medial longitudinal margin (114) and a lateral longitudinal margin (120); and

(c) a second layer (106) of flexible sheet material overlying said electrodes (96, 98) and connected to said first layer (108) along a continuous central strip extending parallel with said electrodes and located between said electrodes, said second layer also being connected to said first layer alongside said lateral longitudinal margin (120) of each of said electrodes, said first and second layers (108, 106) thereby defining a pair of parallel tubes each including one of said electrodes (96, 98), each of said electrodes having an electrically conductive surface exposed within the respective one of said tubes.

2. The sensing pad of Claim 1 wherein said first and second layers are of fluid absorbent material.

3. The sensing pad of Claim 1 wherein said electrodes are adhesively attached to said first layer (108) of fluid absorbent sheet material.

4. The pad of Claim 1, each of said first and second layers (108, 106) having a pair of opposite longitudinally-extending lateral margins (120), and said pad including a third layer (126 or 128) of flexible, fluid-conducting material, said third layer overlying and adhering to one of said first and second layers along said lateral margins thereof.

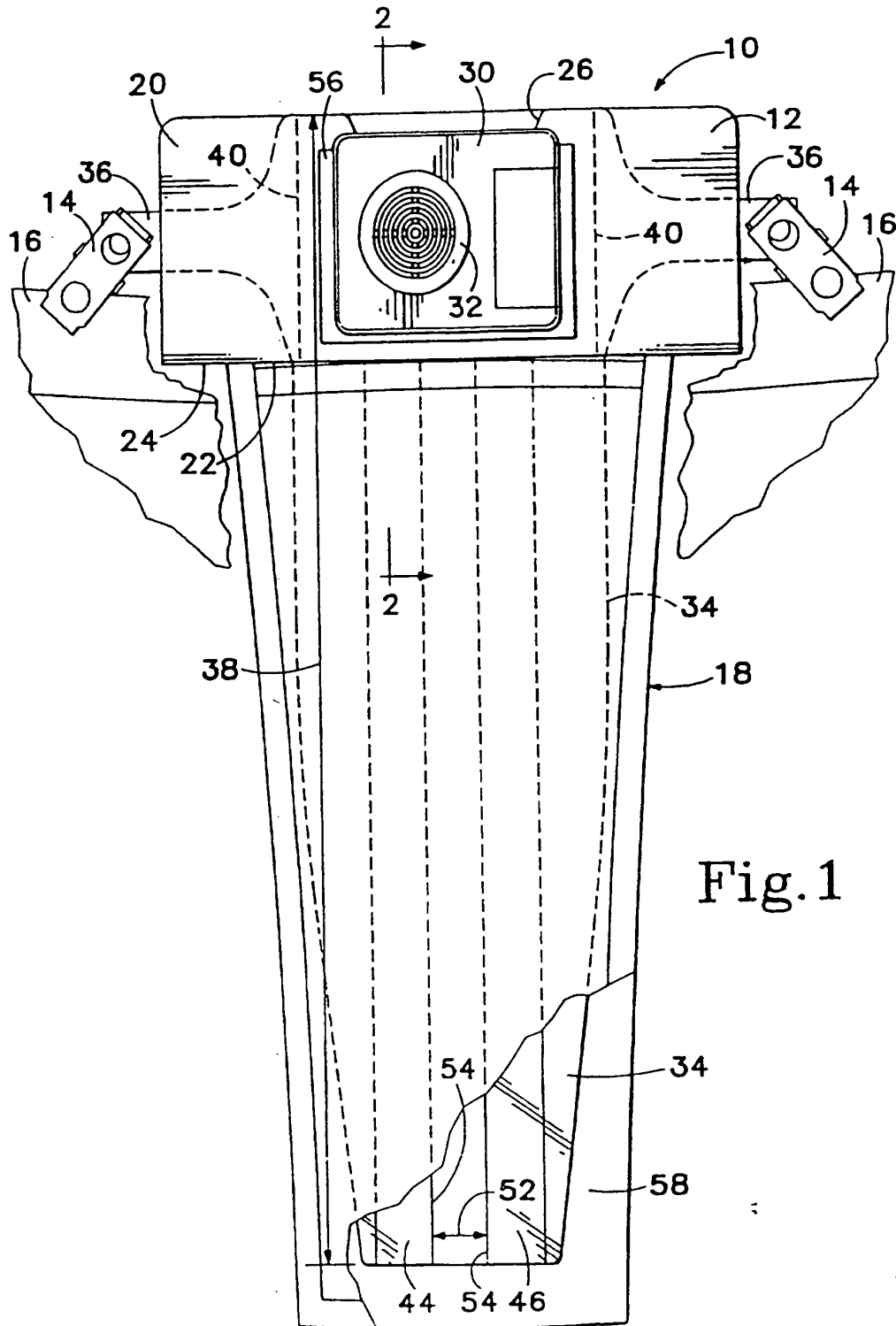
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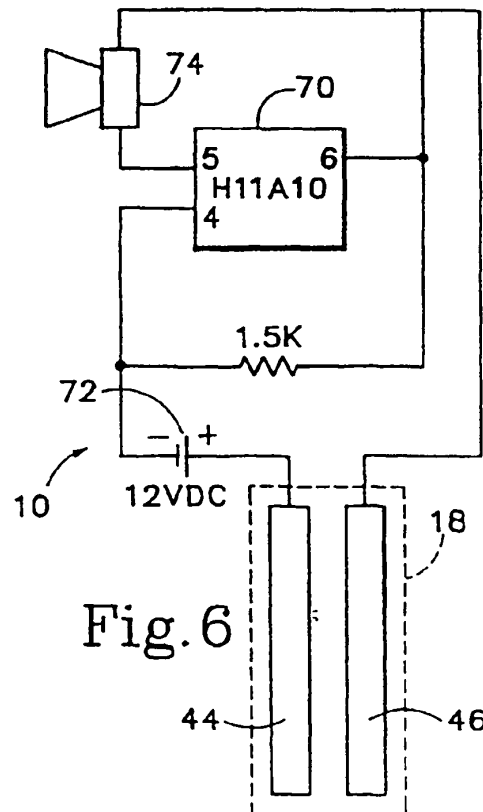
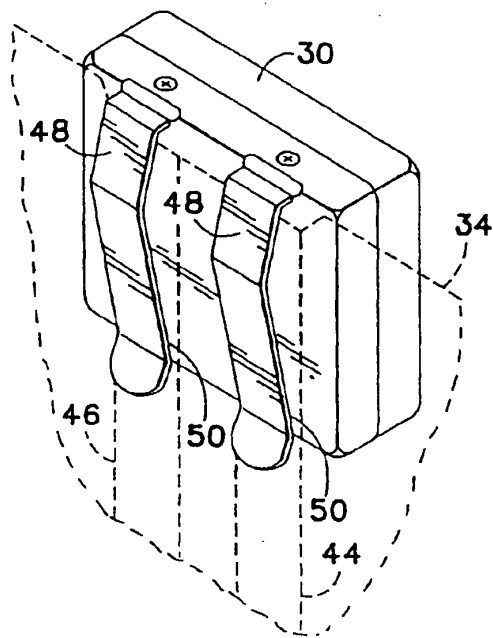
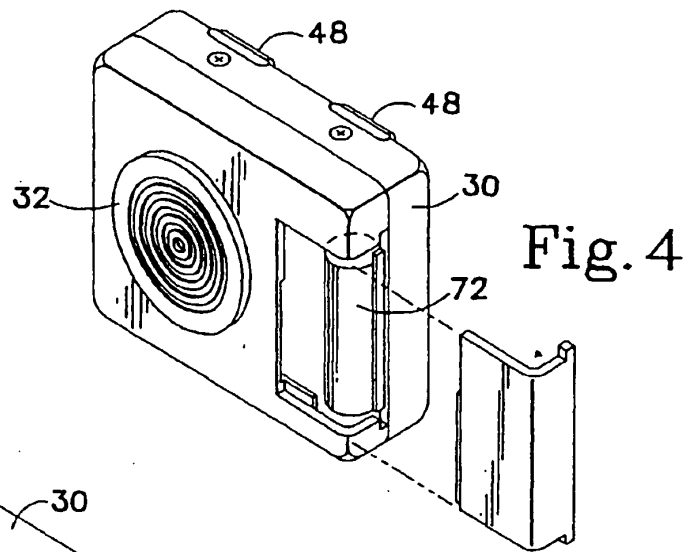
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5. The pad of Claim 4, further including a fourth layer (128 or 126) of flexible, fluid-conducting material, said fourth layer overlying the other one of said first and second layers and adhering thereto along said opposite longitudinally-extending lateral margins thereof.
6. The pad of Claim 1 including an outer face and adhesive means (102) located on said outer face for selectively fastening said pad in a desired position to absorb body fluid originating from a person.
7. Apparatus for detecting the presence of electrically conductive fluid, comprising a sensing pad (94) according to any one of Claims 1 to 6 and signaling means connected electrically to said electrodes, for producing a signal in response to electrical resistance between said electrodes being below a predetermined value.
8. The apparatus of Claim 7 wherein said signaling means includes a vibrator (152) for producing said signal inaudibly.
9. The apparatus of Claim 7 wherein said signaling means includes means for providing said signal visibly.
10. The apparatus of Claim 7 wherein said signaling means includes means for providing said signal in an audible form.
11. The apparatus of Claim 7 wherein said signaling means includes a wireless transmitter.
12. The apparatus of Claim 11 wherein said wireless transmitter transmits said signal on a frequency within a commercial FM broadcast frequency band.
13. The apparatus of Claim 11 or 12, further including a receiver including means for providing a humanly perceptible alarm indication in response to receiving a signal from said wireless transmitter.
14. The apparatus of Claim 11, 12 or 13 wherein said signaling means includes means for producing and transmitting a machine-intelligible message.
15. The apparatus of any one of Claims 7 to 14, including a housing containing said signaling means, and further including a spring finger (48 or 136) mounted on said housing, said spring finger including a contact (138) located thereon, said contact pressing against one of said electrodes (44, 46), said spring finger clamping said one of said electrodes between said spring finger and said housing and said contact thereby connecting said one of said electrodes electrically with said signaling means.
16. The apparatus of Claim 15, including a lever-operated release cam (142) associated with said spring finger.
17. The apparatus of Claim 15 or 16, including a tine (148) for piercing a layer of said fluid-absorbent material and electrically contacting said electrode.
18. The apparatus of any one of Claims 7 to 17 wherein said signaling means includes timing means for limiting the duration of said signal to a predetermined time.
19. The apparatus of any one of Claims 7 to 18 including
 - (a) support means (12) for fastening said apparatus in a desired location; and
 - (b) resilient means (48) mounted on said housing (30) for attaching said housing removably to said support means.
20. The apparatus of Claim 19 wherein said sensing pad is mounted on said support means.
21. The apparatus of Claim 20 wherein a portion of the first layer of the sensing pad is attached to said support means.

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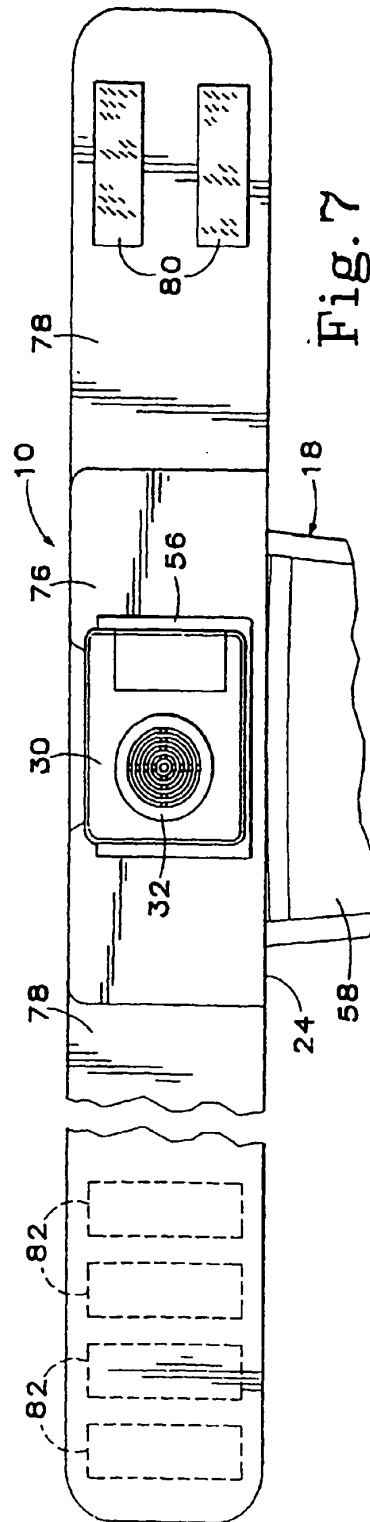
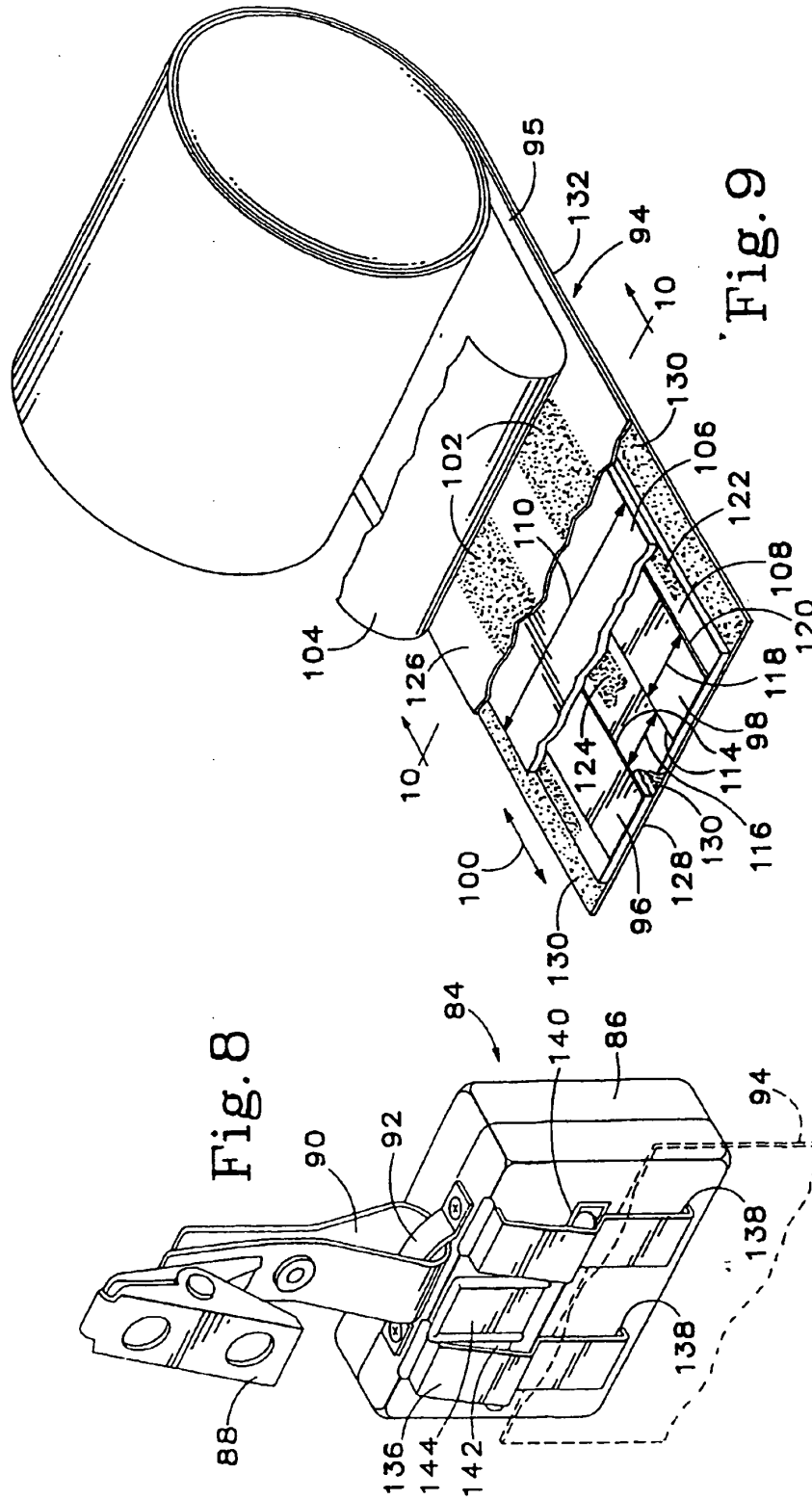


Fig. 7

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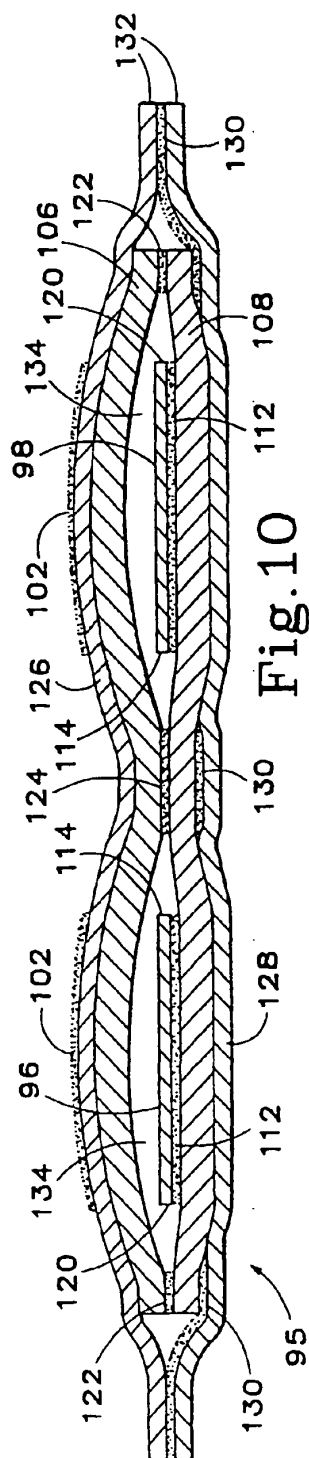


Fig. 10

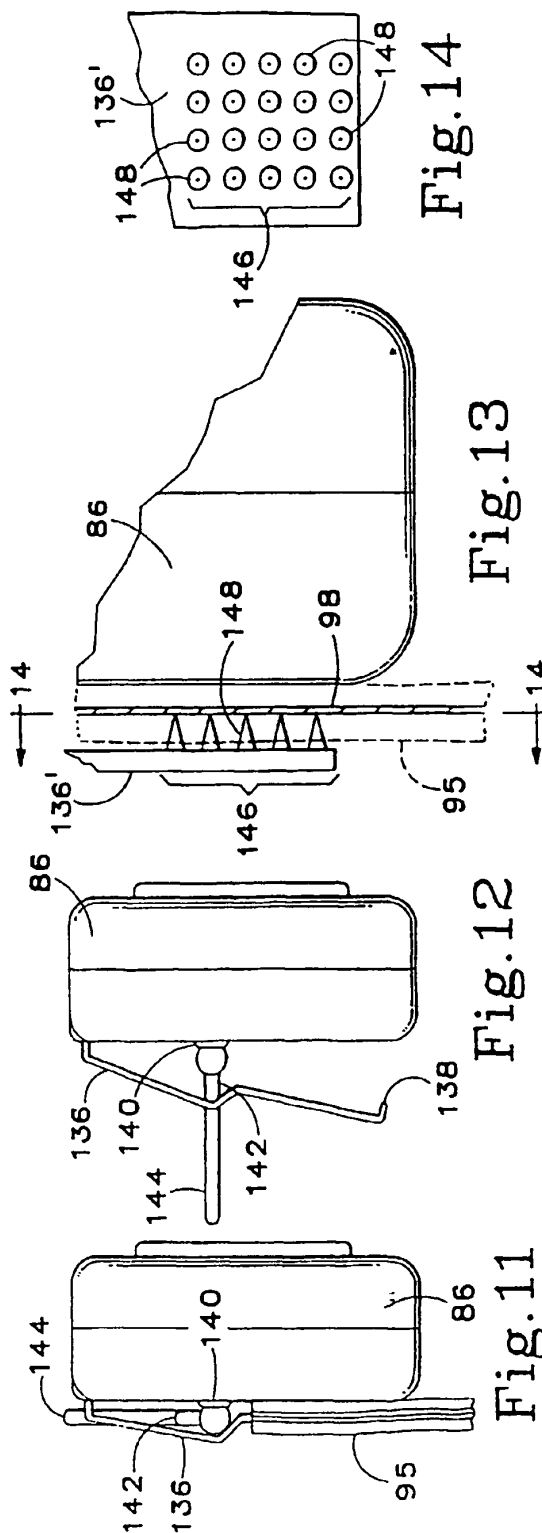


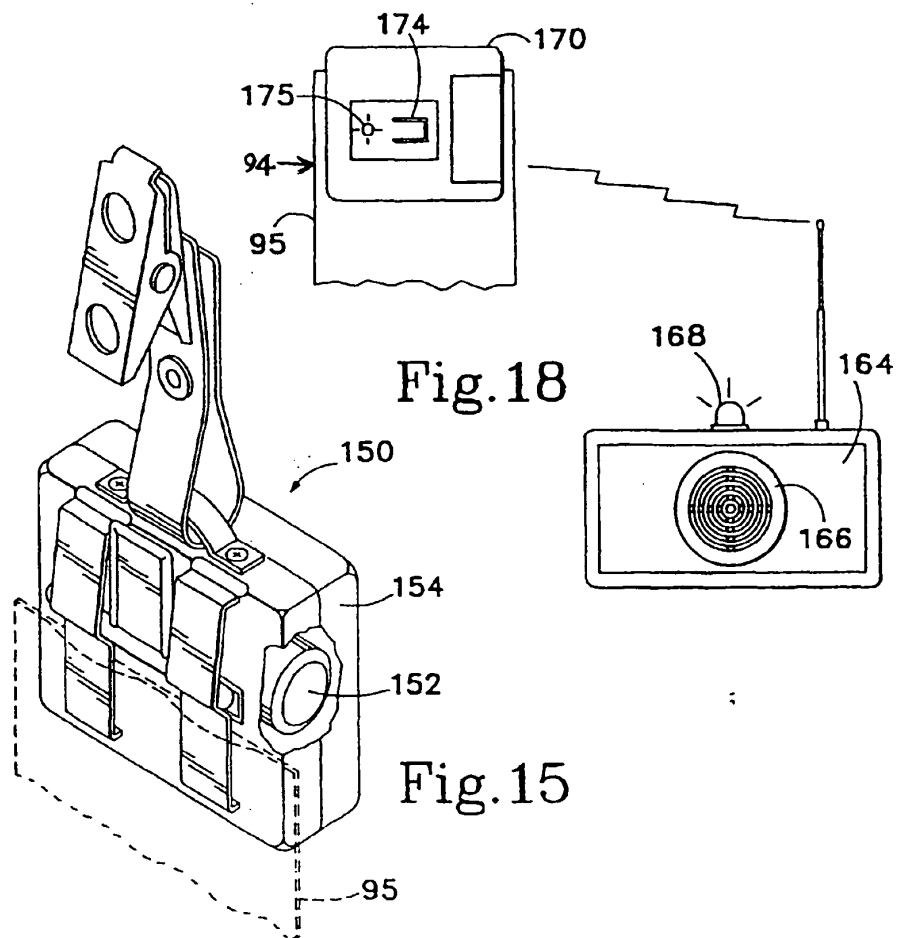
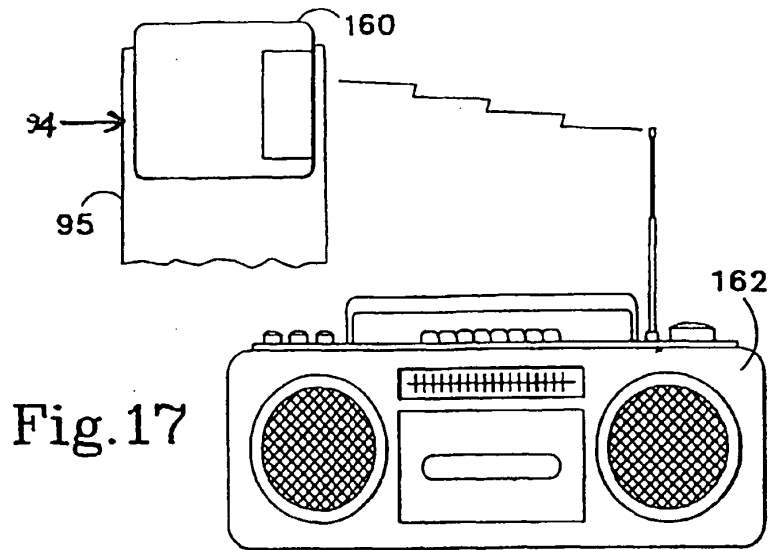
Fig. 11

Fig. 12

Fig. 13

Fig. 14

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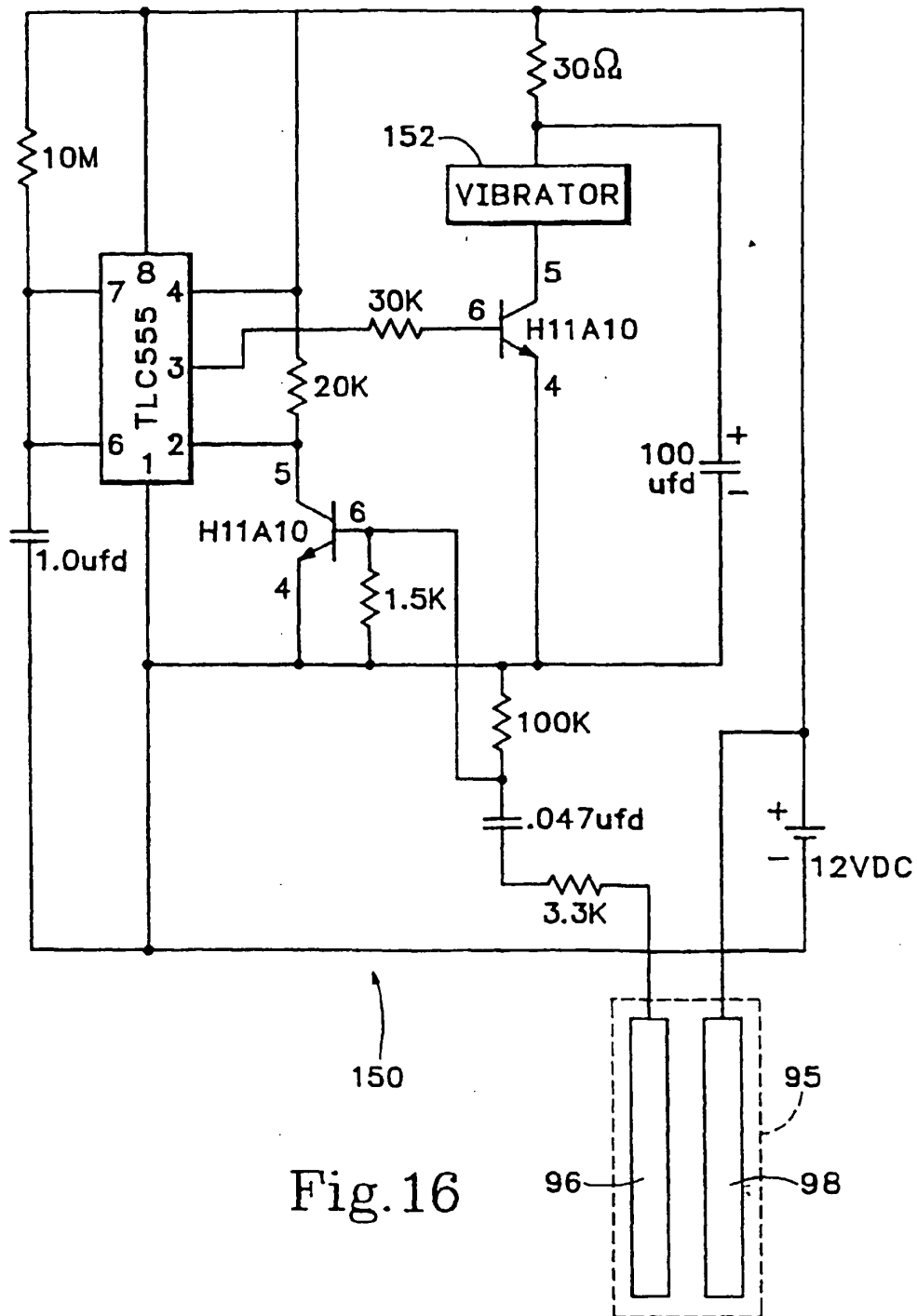
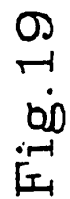


Fig.16



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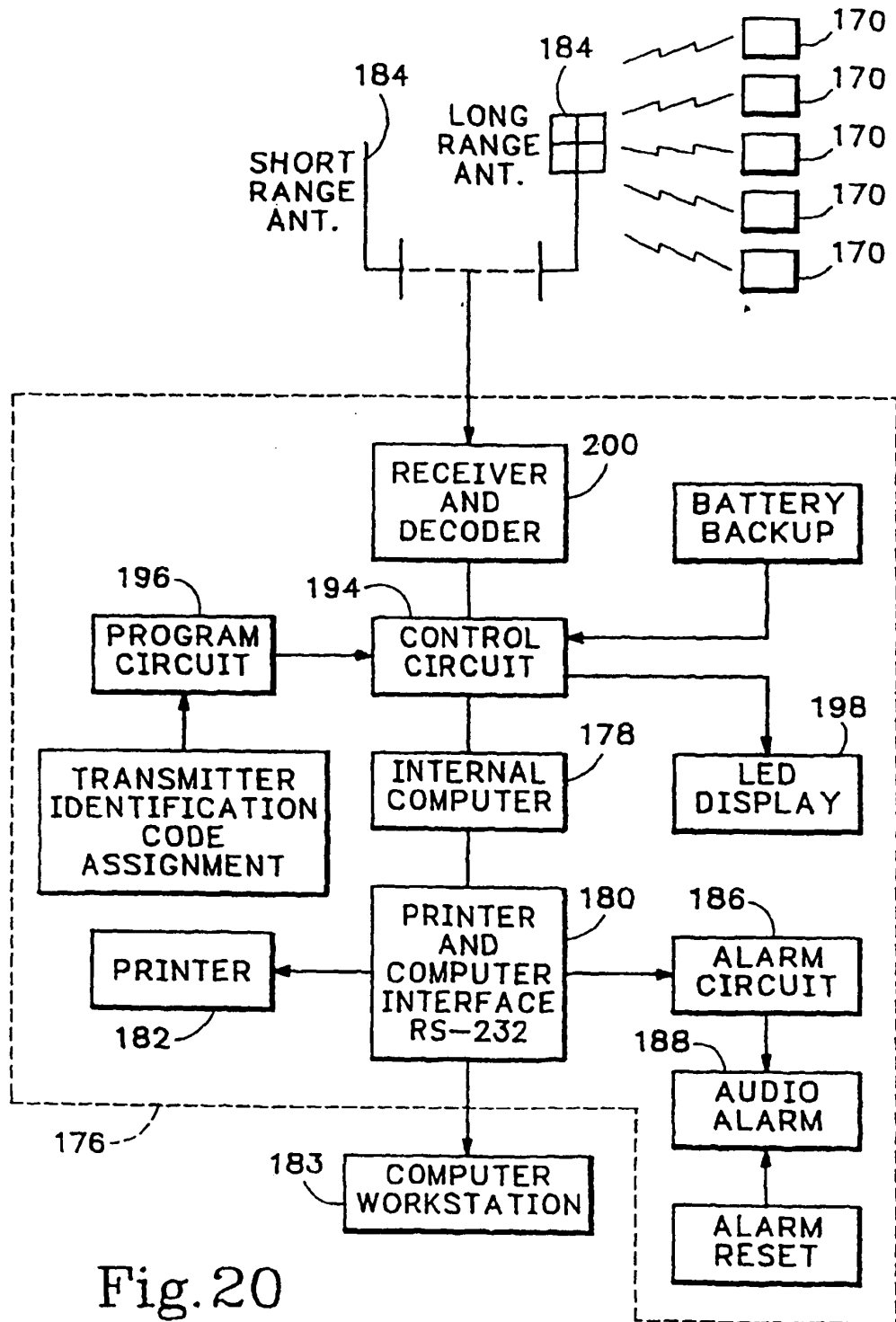
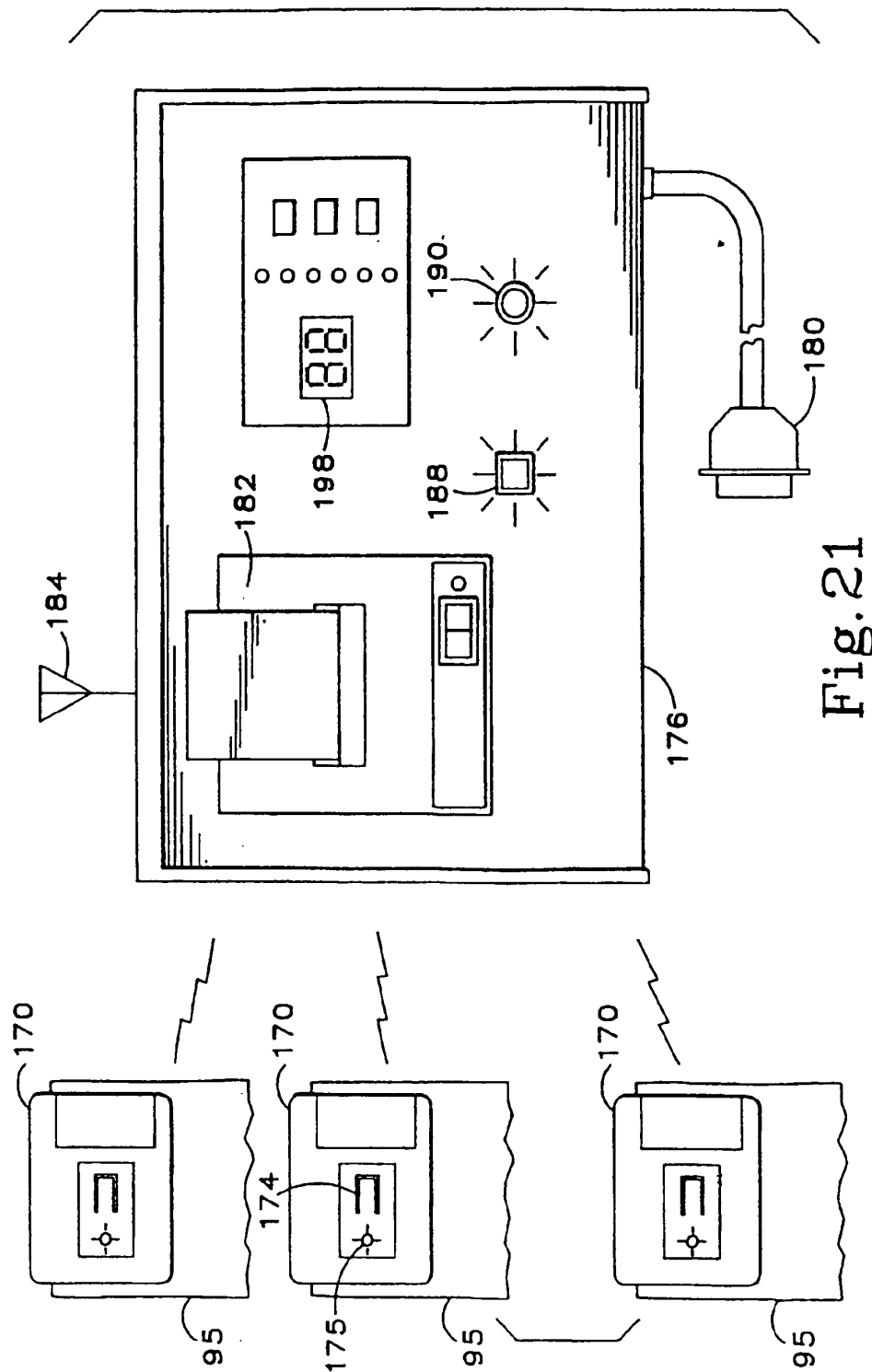


Fig. 20

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EUROPEAN SEARCH REPORT

Application Number
EP 00 11 7526

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**ANNEX TO THE EUROPEAN SEARCH REPORT
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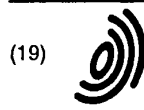
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(54) Moisture-signalling system for diapers

(57) A moisture signalling system for diapers, in which the amount of moisture in the diaper is measured and together with an identification number is radio-graphically transferred by a measuring clip, to be attached to the diaper, having three tongues between which the front side and rear side of the diaper is fastened. The measurement concerns the electrical resistance of a polymer conductor, which is provided in the diaper from the front to the rear, and whose resistance changes by parallel connection of the absorbed moisture. The conductor is also provided on the upper side of the diaper to make contact with the clip in a simple manner. The initial resistance of the conductor indicates that the clip is correctly attached to the diaper. A disposable bag around the clip prevents skin irritation. The supply of the measuring circuit can be drawn actively from a battery or passively from the transmission field of a transmitter/receiver system.

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Description

[0001] This invention relates to a system for in particular remote signalling of moisture in moisture absorbing means such as incontinence diapers, baby diapers, and the like. This invention also relates to a moisture absorbing means, such as a diaper, and a measuring clip of the system.

[0002] Such a system is known inter alia from US 5,557,263.

[0003] For nurses to check whether incontinence diapers need to be changed is very time-consuming because with the current incontinence diapers this check must be done visually. To that end, these diapers are generally provided with a marking indication with a kind of graduation which discolours or disappears if it comes into contact with urine.

[0004] Another known solution to this problem is the so-called pad and buzzer which gives the patient a signal at predetermined time intervals, warning him to go to the toilet.

[0005] From the US patent mentioned, a moisture detection system is known in which via a radiographic connection between a sensor attached to the absorbing means and a receiver, a signal is transferred if moisture is detected. Since, due to the use of moisture absorbing materials that form gels upon moisture uptake, modern incontinence diapers are capable of absorbing large amounts of moisture, it is no longer sufficient to signal that there is moisture in the diaper, but it is necessary to know how much moisture has already been absorbed. According as more moisture is absorbed in the diaper, the area where the gel formation occurs will become larger, and the moisture stain will expand. For logistic reasons, therefore, signalling a quantitative threshold in these diapers is insufficient. Moreover, for hygienic reasons, it is not desirable to provide a reusable sensor in the diaper. For this reason, therefore, a communication means that is attached to the diaper needs to be packaged hygienically, or must be used only a single time.

[0006] The present invention contemplates providing a solution to these problems and to that end is characterized in that the system comprises an electrical conductor which is provided in the moisture absorbing means, the electrical conductor being provided with a conductor material whose resistance is dependent upon an amount of moisture with which the conductor comes into contact, the measuring signalling system further comprising a measuring clip which, in use, is detachably and conductively connected with the electrical conductor, while the measuring clip comprises an electrical circuit for obtaining information about the magnitude of an electrical resistance of the electrical conductor as measured with the electrical circuit, for obtaining information about the amount of moisture in the absorbing means. According to the invention, information is obtained about the amount of moisture in the absorbing system. Moreover, the measuring clip can be

reused.

[0007] The moisture absorbing means such as a diaper for infants or an incontinence diaper is characterized in that it is provided with the conductor of the moisture signalling system.

[0008] The invention also relates to the measuring clip as such of the moisture signalling system. It is adapted to be connected with the moisture absorbing means, such that the electrical circuit of the measuring clip is electrically connected with the conductor of the moisture absorbing means.

[0009] The invention will presently be further elucidated with reference to the drawings. In the drawings:

Fig. 1 schematically shows a diaper provided with a sensor according to the invention;

Fig. 2A shows a measuring clip with which the measured value is transmitted to a receiving system, also shown; and

Fig. 2B shows a side view of the measuring clip according to Fig. 2A

[0010] Determining the amount of moisture in a moisture absorbing means, such as a diaper, preferably occurs, according to the invention, by measuring the electrical resistance of a conductor provided in the diaper. This conductor consists of a material of a relatively high electrical resistance. Suitable for this purpose are, for instance, coatings of conductive polymers such as polyaniline and polypyrrole. This coating may be provided on a tape which is secured in the diaper. The coating may also be sprayed via a spray nozzle directly onto the carrier material of the diaper in the form of a narrow track or may optionally even be provided integrally on this carrier material.

[0011] Instead of using conductive polymer for the conductor, it is also possible to use a very thin electrically conductive metal or metal oxide layer sputtered onto a tape.

[0012] The measurement of the electrical resistance of the conductor is done, according to the invention, with the aid of a measuring clip which is provided with an electrical circuit comprising a measuring circuit and means for transferring the measured value by contactless route to a receiving system which processes the values received, possibly coming from several diapers, and optionally passes a signal to an attendant.

[0013] The principle of the measurement according to the invention of the amount of moisture present in the diaper is based on the phenomenon that a part of the electrical resistance of the conductor obtains a low parallel resistance and, as it were, is short-circuited by the moisture present, yielding a decrease of the electrical resistance measured over the conductor. The moisture here forms a resistance which is connected in parallel with (a part of) the conductor material of the conductor, so that the resistance of the conductor is reduced as a result of the moisture. The conductor preferably extends

between a front and a rear side of the diaper. To make this reduction of the electrical resistance independent of the position where the moisture is present in the diaper, the electrical resistance is preferably measured over a path from the front to the rear of the diaper.

[0014] The place where the front and the rear of the diaper meet and where, accordingly, the measuring clip is to be preferably attached is the portion where the adhesive strips are situated and where the front and rear of the diaper overlap by a small portion. To have greater freedom regarding the position where the clip is to be fitted, the conductor is preferably provided on the upper side, both at the front and the rear, so as to extend horizontally over a portion.

[0015] Fig. 1 schematically shows a diaper 2 and the manner in which the diapers are produced while mutually attached. On a carrier foil 4 of the diaper, a conductor 6 is provided, which consists of a tape provided with conductive polymer coating of a relatively high resistance. To obtain a horizontal connecting portion, the conductor 6, both along a front side 8 and along a rear side 10 of the diaper, is laid over a certain portion 12, 14 along an upper side 16, 18 of the diaper. By cutting out the diapers at the end of the production line, there is obtained for each diaper 2 a conductor 6 from the front to the rear, whose total electrical resistance is dependent on the initial electrical resistance of the conductive material of the conductor, measured in dry condition, and the magnitude of a moisture stain present. Obviously, the conductive coating can also be applied directly to the diaper material via one or more spray nozzles or by way of transfer rollers. Also, the conductor 6 can be provided integrally on the carrier foil 4, which, however, necessitates a greater square resistance value of the coating to obtain sufficient measuring accuracy.

[0016] The connection of the clip 22 occurs preferably, as indicated in Figs. 2A and 2B, by means of electrical contacts which are made of needle-shaped design, in this example thin needles 24A and 24B, which are provided on at least three guide tongues 26, 28 and 30 of the clip or peg 22. The tongues 26 and 28 form a first pair of tongues and the tongues 28 and 30 form a second pair of tongues. When fitting the diaper, the upper side 18 of the rear side 10 of the diaper 2 with the horizontal portion 14 of the conductor 6 thereon is slipped between the tongues 26 and 28, and the upper side 16 of the front side 8 of the diaper 2 with the likewise horizontal portion 12 of the conductor 6 thereon is slipped between the tongues 28 and 30. The needles 24B, 24A on the back and front of the middle tongue 28, respectively, are electrically insulated from each other and respectively electrically connected with the needles 34B on the tongue 26 and the needles 24A on the tongue 30. A measuring circuit 36 in the clip having attached thereto a contactless radio-frequency communication means 38 in the clip is now connected via conductors 40, 42 in the tongues 26, 28 and 30 with ends 32, 34 of

the conductor 6 which is provided in the diaper. Because presently a more or less known electrical resistance value is measured, the measuring circuit 36 in the clip 2 switches on and will, for instance at predetermined time intervals, transmit the measured value of the electrical resistance, or a measuring value related to the electrical resistance value of the conductor 6 measured in dry condition, to a receiving system 44, which converts the received measuring value into a signalling to an attendant. This signalling can, for instance, be done exclusively if a particular moisture threshold quantity is exceeded.

[0017] By slightly varying the time intervals between the transmissions of the measuring values, and transmitting together with this measuring value an identity number of the measuring clip as stored in the electrical circuit formed by the measuring circuit 36 and the communication means 38, measuring values of several diapers 2 can be distinguishably transmitted to one and the same receiving system 44. This requires the time intervals for transmission to be relatively long with respect to the time needed for transmitting a single measuring report.

[0018] A great advantage of the measuring method according to the invention is further that with the same system it can be determined whether the clip 2 is correctly fitted on the diaper, because if it is improperly fitted, either a short-circuit with too low an electrical resistance, or too high an initial electrical resistance is measured.

[0019] From the viewpoint of hygiene, and to prevent skin irritation due to the clip, as well as to enhance wearing convenience, optionally use can be made of a disposable bag in which the clip is placed prior to being fitted, and which is pierced by the needles making contact with the conductor in the diaper.

[0020] The communication between the clip 22 and the receiving system 44 can occur actively, with the supply of the measuring circuit in the clip 22 and the transfer to the receiving system 44 proceeding from a small battery. To bridge a largest possible distance, preferably use is made of a relatively high transmission frequency of, for instance, 433 MHz. It is also possible to have the clip 22 function passively, with the energy for the measurement and for the transfer of the measuring value being obtained from an interrogation field of the receiving system 44. To that end, the communication means 38 may be provided with a resonant circuit known per se. Communication between the clip 22 and the receiving system 44 can then take place in a manner based both on the absorption and on the transmission principle. The distance that can then be bridged is small in proportion to the active transfer, and the antenna of a passive clip is more complex in connection with the much lower frequency that is necessary in a passive system.

[0021] The moisture signalling system according to the invention for moisture absorbing means such as dia-

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pers: therefore comprises an electrical conductor 6 which is provided in the moisture absorbing means 2, in this example the diaper. The electrical conductor is provided with a conductive material, while the resistance of the conductor is dependent upon the amount of moisture with which the conductive material comes into contact. The measuring signalling system further comprises the measuring clip 22 which, in use, is detachably and electrically conductively connected with the electrical conductor. The measuring clip 22 comprises an electrical circuit 36, 38 for obtaining, by means of a measurement, information about the magnitude of an electrical resistance of the electrical conductor 6 as measured with the electrical circuit 36, 38, for obtaining information about the amount of moisture in the moisture absorbing means 4. Preferably, the conductor extends between the front side 8 and the rear side 10 of the moisture absorbing means. The conductive material of the conductor 6 has a higher electrical resistance with respect to the electrical resistance of the moisture to be absorbed by the moisture absorbing means, so that the total electrical resistance of the conductor decreases by the connection of the electrical resistance of the moisture absorbed in the absorbing means in parallel with the conductive material. As a result, changes in the electrical resistance of the conductor as measured by the electrical circuit 36, 38 are rendered independent of the position where the moisture is located in the moisture absorbing means. The above-mentioned information about the magnitude of the measured electrical resistance can comprise, for instance, the change of the electrical resistance relative to an initial value of the electrical resistance when the diaper is still dry. (The resistance of the dry conductive material.) However, the above-mentioned information can also comprise the magnitude of the measured electrical resistance as such. The information referred to here is understood to include a quantity, or a change of a quantity, which can be respectively derived from the electrical resistance, or the change of the electrical resistance. Such variants are all understood to fall within the scope of the invention. The moisture signalling system in this example further comprises the receiving system 44, while the electrical circuit 36, 38 of the measuring clip for obtaining the above-mentioned information about the electrical resistance of the conductor is further adapted for the wireless transmission of the information about the measured electrical resistance, and hence about the measured amount of moisture, to the receiving system 44. The receiving system can generate a signal when the measured amount of moisture exceeds a particular threshold value. In particular, it holds that the electrical circuit 36, 38 is further adapted for transmitting an identification code of the measuring clip. In this way, the measuring clip which feeds the above-mentioned information about the amount of moisture in the moisture absorbing means to the receiving system 44 can be identified. In that case, also the absorbing means in

question is identified, and so is the person wearing it. An attendant, upon receiving a signal from an identified measuring clip, can proceed to take focused action, for instance by replacing the moisture absorbing means by a clean moisture absorbing means.

[0022] The receiving system 44 in this example is further adapted for generating an electromagnetic interrogation field. The electrical circuit 36, 38 of the measuring clip in this example is preferably designed as a passive circuit with a resonant circuit that responds when this circuit is introduced into the electromagnetic interrogation field. Thus the electrical circuit draws energy from the electromagnetic interrogation field in order to function. In that case, no battery is needed, as is the case in an active system.

[0023] As mentioned, the electrical circuit can also be designed as an active circuit with a battery. The advantage of this is that the distance between the measuring clip and the receiving system 44 can be greater than when the measuring clip is provided with a passive electrical circuit.

[0024] In particular, it holds that the electrical circuit 36, 38 of the measuring clip is adapted for periodically transferring information about the measured amount of moisture. This can be carried out, for instance, once every 15 minutes.

[0025] In particular, it holds that the measuring clip comprises at least a first and a second pair of tongues 26, 28, the first pair of tongues being adapted, in use, to encompass a portion of a front side 8 of the absorbing means which, for instance, is in overlap with a rear side 10 of the absorbing means. The second pair of tongues 28, 30 is adapted, for instance, to encompass, in use, a portion of the rear side 10 of the absorbing means which, for instance, is in overlap with the above-mentioned front side of the absorbing means. The tongues are then preferably provided with the electrical contacts which, for instance, are of needle-shaped design, and project from the tongues and which connect the electrical conductor 6, in use, electrically with the electrical circuit 36, 38 of the measuring clip. The clip 22 can also be designed such that the first pair of tongues make contact with a first portion of the conductor 6, while the second pair of tongues make contact with a second portion of the conductor 6, which portions are different from each other.

[0026] In particular, and preferably, these portions are the respective ends 32, 34 of the conductor 6. However, this is not requisite. In the latter case, the clip 22 can be designed such that the first and the second pair of tongues have one tongue in common. In fact, in that case, in use, the ends 32 and 34 of the conductor overlap each other (and the above-mentioned portions of the front and rear side of the moisture absorbing means overlap) and can therefore be connected with each other by means of a clip with three tongues located above each other, as shown in Fig. 2B. The first pair of tongues and the second pair of tongues may also com-

prise no common tongue, in which case it is possible, in principle, to connect, besides the above-mentioned end 32 and 34, other mutually different parts of the conductor with the measuring circuit 36.

[0027] Preferably, the moisture signalling system is adapted to check whether the measuring clip is properly electrically connected with the conductor. This can be done by measuring the initial resistance of the conductor (this is the dry resistance of the conductive material if the measuring clip is correctly connected) by means of the measuring clip. Measuring the initial resistance and deciding whether it is correct can be carried out by the electrical circuit 36, 38. The moisture signalling system can be adapted for initialising the measurement of the amount of moisture when the measured initial resistance agrees within predetermined limits with the expected initial value. Determining whether a measured initial resistance is within the predetermined limits can be carried out both by the electrical circuit 36, 38 itself and by the receiving device 44.

[0028] Preferably, the measuring clip is included in a replaceable bag of, for instance, plastic.

[0029] In that case, the above-mentioned electrical contacts, i.e. the needles 24A, 24B will have been caused to pierce the bag in question. When the moisture absorbing means, in this example the diaper, is to be replaced, the measuring clip can be removed together with the bag. Thereafter the bag is discarded and a new bag is fitted around the measuring clip. The above-mentioned needles are then caused to pierce the bag again. Thereafter a person is provided with a clean moisture absorbing means. After this moisture absorbing means, in particular the diaper, has been fitted, the measuring clip with the bag can be fastened to the moisture absorbing means, such that the electrical circuit 36, 38 of the clip is connected with the conductor 6 of the newly fitted clean moisture absorbing means.

[0030] The conductor can comprise, for instance, a tape, which is provided with an electrically conductive polymer. It is also possible, however, that the conductor is provided with a coating of electrically conductive polymer which has been sprayed as a track in the moisture absorbing means. Further, it is possible that the conductor is provided with a tape having sputtered thereon a thin electrically conductive metal or metal oxide layer. As shown in Fig. 1, further, the conductor preferably extends along an upper side 18 of a rear side 10, from the rear side 10 to the front side 8, and along an upper side 16 of the front side 8 of the moisture absorbing means. It is also conceivable that the conductor is provided with other conductive materials, for instance conductive materials whose resistance is dependent in any other way on the amount of moisture with which it comes in contact. The electrical circuit 36, 38 and/or the receiving means 44 can then be adjusted accordingly. Such variants are all understood to fall within the scope of the invention.

Claims

1. A moisture signalling system for in particular remote signalling of moisture in moisture absorbing means such as diapers, characterized in that the system comprises an electrical conductor which is provided in the moisture absorbing means, the electrical conductor being provided with a conductor material, the resistance of the conductor being dependent on an amount of moisture with which the conductor material comes into contact, the moisture signalling system further comprising a measuring clip which, in use, is detachably and electrically conductively connected with the conductor, while the measuring clip comprises an electrical circuit for obtaining information, by means of a measurement, about the magnitude of an electrical resistance of the electrical conductor, for obtaining information about the amount of moisture in the absorbing means.
2. A moisture signalling system according to claim 1, characterized in that the conductor extends between a front side and a rear side of the moisture absorbing means.
3. A moisture signalling system according to claim 2, characterized in that the conductor material has a high electrical resistance relative to the electrical resistance of the moisture to be absorbed by the moisture absorbing means, so that the total electrical resistance of the conductor decreases through parallel connection of the electrical resistance of moisture absorbed in the moisture absorbing means with the conductor material, so that the change in the electrical resistance of the conductor as measured by the electrical circuit is independent of the position where the moisture is located in the moisture absorbing means.
4. A moisture signalling system according to any one of the preceding claims, characterized in that said information about the magnitude of the measured electrical resistance comprises the change of the electrical resistance relative to an initial value of the electrical resistance.
5. A moisture signalling system according to any one of the preceding claims, characterized in that the system further comprises a receiving system, while the electrical circuit of the measuring clip for obtaining the information about the electrical resistance of the conductor is further adapted for wireless transmission of this information about the measured electrical resistance, and hence about the measured amount of moisture, to the receiving system.
6. A moisture signalling system according to claim 5,

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characterized in that the receiving system generates a signal when the measured amount of moisture exceeds a threshold value.

7. A moisture signalling system according to claim 5 or 6, characterized in that the electrical circuit is further adapted for transmitting an identification code of the measuring clip to the receiving system.
8. A moisture signalling system according to any one of claims 5-7, characterized in that the receiving system is further adapted for generating an electromagnetic interrogation field, while the electrical circuit of the measuring clip is designed as a passive circuit having a resonant circuit which responds when this circuit is introduced into the electromagnetic interrogation field.
9. A moisture signalling system according to any one of claims 5-7, characterized in that the electrical circuit is designed as an active circuit with a battery.
10. A moisture signalling system according to any one of claims 5-9, characterized in that the electrical circuit of the measuring clip is adapted for periodically transferring the information obtained by means of the electrical circuit.
11. A moisture signalling system according to any one of the preceding claims, characterized in that the measuring clip comprises at least a first and second pair of tongues, the first pair of tongues being adapted, in use, to encompass a portion of a front side of the moisture absorbing means, and the second pair of tongues being adapted, in use, to encompass a portion of a rear side of the absorbing means, while the tongues are provided with electrical contacts which connect the electrical conductor electrically with the electrical circuit of the measuring clip.
12. A moisture signalling system according to claim 11, characterized in that the electrical contacts are of needle-shaped design and project from the tongue.
13. A moisture signalling system according to claim 2 and according to claims 11 or 12, characterized in that the first and second pair of tongues comprise a common tongue which is located between the other tongues of the first and second pair, for respectively comprising the portion of the front side and the portion of the rear side, while these portions, in use, are in mutual overlap.
14. A moisture signalling system according to any one of the preceding claims, characterized in that the moisture signalling system is adapted for checking whether the measuring clip is properly electrically

connected with the conductor by measuring the initial resistance of the conductor by means of the measuring clip.

15. A moisture signalling system according to claims 14, characterized in that the moisture signalling system is adapted for switching on the electrical circuit for measuring the amount of moisture when the measured initial resistance agrees within predetermined limits with an expected initial resistance.
16. A moisture signalling system according to any one of the preceding claims, characterized in that the measuring clip is included in a replaceable bag of, for instance, plastic.
17. A moisture signalling system according to claims 12 and 16, characterized in that the electrical contacts have been caused to pierce the bag.
18. A moisture signalling system according to any one of the preceding claims, characterized in that the conductor comprises a tape which is provided with an electrically conductive polymer.
19. A moisture signalling system according to any one of the preceding claims 1-17, characterized in that the conductor is provided with a coating of an electrically conductive polymer which has been sprayed as a track in the moisture absorbing means.
20. A moisture signalling system according to any one of claims 1-17, characterized in that the conductor is provided with a tape having sputtered thereon a thin electrically conductive metal or metal oxide layer.
21. A moisture signalling system according to any one of the preceding claims, characterized in that the conductor respectively extends along an upper side of a rear side, from the rear side to a front side, and along an upper side on the front side of the moisture absorbing means.
22. A moisture absorbing means, such as a diaper for infants or an incontinence diaper, provided with an electrical conductor of the moisture signalling system according to any one of the preceding claims.
23. A moisture absorbing means according to claim 22, characterized in that the conductor extends between a front side and a rear side of the moisture absorbing means.
24. A moisture absorbing means according to claim 23, characterized in that a conductor material of the conductor has a high electrical resistance relative to the electrical resistance of the moisture to be

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absorbed by the absorbing means, so that the total electrical resistance of the conductor decreases by parallel connection of the electrical resistance of moisture absorbed in the absorbing means and the conductor material.

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25. A moisture absorbing means according to any one of the preceding claims 22-24, characterized in that the conductor comprises a tape which is provided with an electrically conductive polymer.

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26. A moisture absorbing means according to any one of the preceding claims 22-24, characterized in that the conductor is provided with a coating of electrically conductive polymer which has been sprayed as a track in the moisture absorbing means.

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27. A moisture absorbing means according to any one of claims 22-24, characterized in that the conductor is provided with a tape having sputtered thereon a thin electrically conductive metal or metal oxide layer.

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28. A moisture absorbing means according to any one of the preceding claims 22-27, characterized in that the conductor respectively extends along an upper side of a rear side, from the rear side to a front side, and along an upper side on the front side of the moisture absorbing means.

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29. A measuring clip of the moisture signalling system according to any one of the preceding claims 1-21.

30. A measuring clip according to claim 29, characterized in that the measuring clip is adapted to be connected with a moisture absorbing means, such that an electrical circuit of the measuring clip is electrically connected with an electrical conductor of the moisture absorbing means which extends from a front side to a rear side of the moisture absorbing means.

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31. A measuring clip according to claim 30, characterized in that the measuring clip is provided with at least a first and second pair of tongues, the first pair of tongues being adapted, in use, to encompass a portion of a front side of the moisture absorbing means and the second pair of tongues being adapted, in use, to encompass a portion of a rear side of the moisture absorbing means, the tongues being provided with electrical contacts which connect the conductor of the moisture absorbing means electrically with the electrical circuit of the measuring clip.

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32. A measuring clip according to claim 31, characterized in that the electrical contacts are of needle-shaped design and project from the tongue.

33. A measuring clip according to claim 31 or 32, characterized in that the first and second pair of tongues comprise a common tongue which is located between the other tongues of the first and second pair.

34. A measuring clip according to any one of claims 30-33, characterized in that the electrical circuit is adapted for obtaining, by means of a measurement, information about the magnitude of an electrical resistance of the electrical conductor for obtaining information about the amount of moisture in the absorbing means.

35. A measuring clip according to claim 34, characterized in that the electrical circuit of the measuring clip for obtaining the information about the electrical resistance of the conductor is further adapted for the wireless transmission of this information to a receiving system.

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FIG. 1

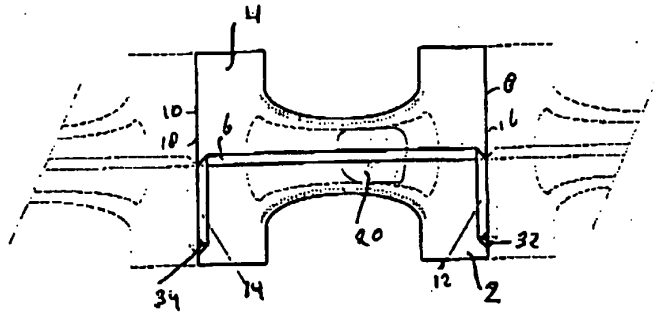


FIG. 2A

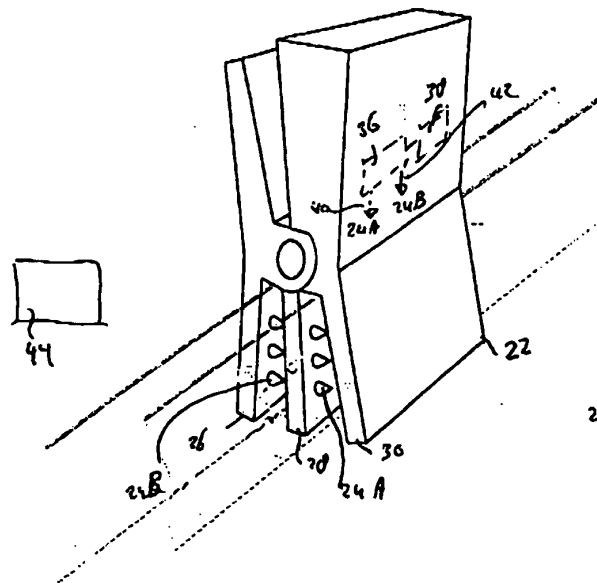
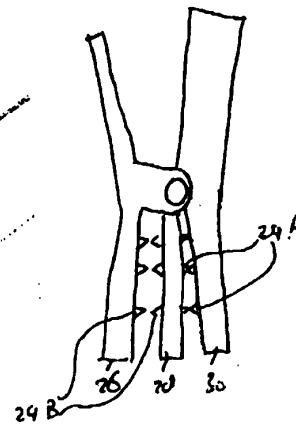


FIG. 2B



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EUROPEAN SEARCH REPORT

Application Number
EP 00 20 1445

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Place of search THE HAGUE		Date of completion of the search 14 August 2000	Examiner Kelperis, K
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82



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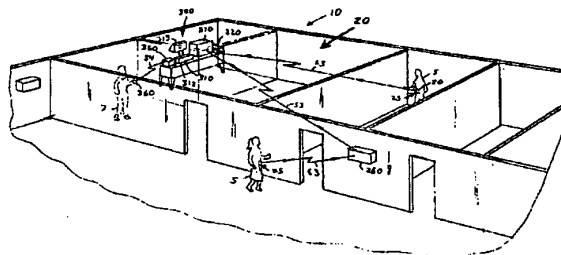
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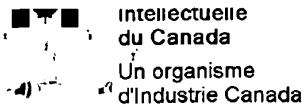
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(54) **SYSTEME DE CONTROLE HYGROMETRIQUE**
(54) **WETNESS MONITORING SYSTEM**

(57)

The present invention relates to a wetness monitoring system that includes a data collection device that sends wetness measurement data to a central computer that detects changes in wetness measurement data caused by the presence of urine or other dielectric fluids. The data collection device includes a semi-reusable sensor and reusable data collector that are worn on a garment of the person. The data collector includes an internal power source so that the person can live a normal ambulatory life. The data collector has an electrical circuit that uses the changing resistance characteristics in the sensor to gather wetness measurement data. The data collector periodically generates and transmits a signal containing the actual wetness measurement data. The signals are coded to identify the particular data collector or person sending the signal. The data collector is programmed to conserve power by sending signals less frequently during periods when the sensor is clearly dry. Signals are sent more frequently when the sensor is damp or a wetness event may have occurred. The central computer receives the signals containing the wetness measurement data and compares the measurement data to an adjustable wetness sensitivity level to determine if a wetness event has occurred. When the central computer determines that a wetness event has occurred, the computer displays the name of the particular person wearing the data collector and the approximate time that the wetness event occurred. The system then pages an appropriate healthcare worker to inform them that the particular individual needs attention and tracks the approximate response times to ensure that the patient is continuously receiving prompt care.





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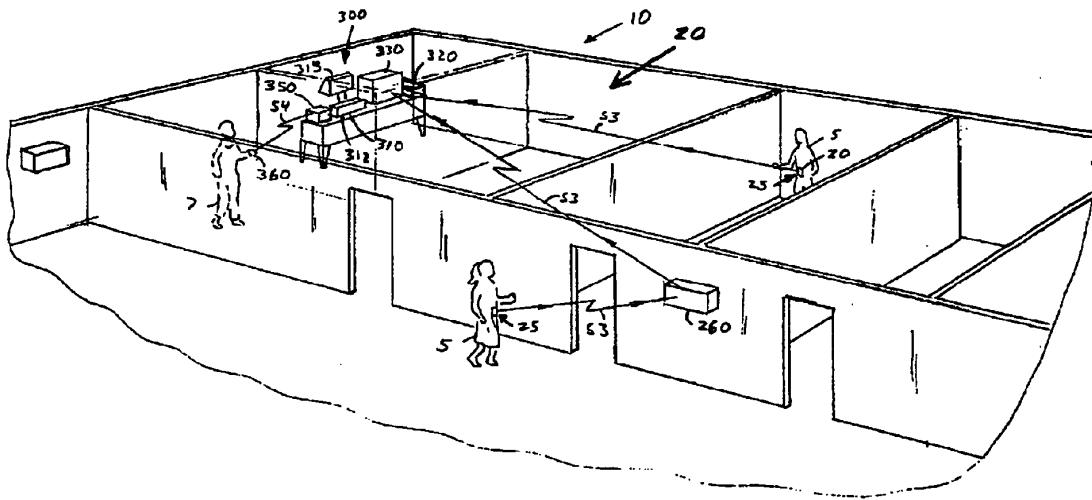
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(54) Titre : SYSTEME DE CONTROLE HYGROMETRIQUE
(54) Title: WETNESS MONITORING SYSTEM

(57) Abrégé/Abstract:

The present invention relates to a wetness monitoring system that includes a data collection device that sends wetness measurement data to a central computer that detects changes in wetness measurement data caused by the presence of urine or other dielectric fluids. The data collection device includes a semi-reusable sensor and reusable data collector that are worn on a garment of the person. The data collector includes an internal power source so that the person can live a normal ambulatory life. The data collector has an electrical circuit that uses the changing resistance characteristics in the sensor to gather wetness measurement data. The data collector periodically generates and transmits a signal containing the actual wetness measurement data. The signals are coded to identify the particular data collector or person sending the signal. The data collector is programmed to conserve power by sending signals less frequently during periods when the sensor is clearly dry. Signals are sent more frequently when the sensor is damp or a wetness event may have occurred. The central computer receives the signals containing the wetness measurement data and compares the measurement data to an adjustable wetness sensitivity level to determine if a wetness event has occurred. When the central computer determines that a wetness event has occurred, the computer displays the name of the particular person wearing the data collector and the approximate time that the wetness event occurred. The system then pages an appropriate healthcare worker to inform them that the particular individual needs attention and tracks the approximate response times to ensure that the patient is continuously receiving prompt care.

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ABSTRACT

The present invention relates to a wetness monitoring system that includes a data collection device that sends wetness measurement data to a central computer that detects changes in wetness measurement data caused by the presence of urine or other dielectric fluids. The data collection device includes a semi-reusable sensor and reusable data collector that are worn on a garment of the person. The data collector includes an internal power source so that the person can live a normal ambulatory life. The data collector has an electrical circuit that uses the changing resistance characteristics in the sensor to gather wetness measurement data. The data collector periodically generates and transmits a signal containing the actual wetness measurement data. The signals are coded to identify the particular data collector or person sending the signal. The data collector is programmed to conserve power by sending signals less frequently during periods when the sensor is clearly dry. Signals are sent more frequently when the sensor is damp or a wetness event may have occurred. The central computer receives the signals containing the wetness measurement data and compares the measurement data to an adjustable wetness sensitivity level to determine if a wetness event has occurred. When the central computer determines that a wetness event has occurred, the computer displays the name of the particular person wearing the data collector and the approximate time that the wetness event occurred. The system then pages an appropriate healthcare worker to inform them that the particular individual needs attention and tracks the approximate response times to ensure that the patient is continuously receiving prompt care.

WETNESS MONITORING SYSTEM

TECHNICAL FIELD OF THE INVENTION

This invention relates to a wetness monitoring system with a data collection device that attaches to a garment of an individual to gather and transmit wetness measurement data to a central computer system that determines when a wetness event occurs, notifies appropriate healthcare workers, and tracks approximate response times to ensure that the individual is consistently receiving proper care.

BACKGROUND OF THE INVENTION

Families, assisted living homes and hospitals continually strive to provide the best care they can for their loved ones, residents and patients. Yet, providing basic care such as feeding, bathing and clothing a person can be time consuming, unpleasant and unrewarding. Perhaps the least favored of these tasks is changing a diaper or garment of a person that has been rendered incontinent. Still, these tasks must be done well and in a timely manner for the person to receive proper care. Products and systems that help deliver a consistently high level of basic care can be valuable aids to the people rendering these services. Safe, economical and easy to use products and systems that help achieve these results are typically well received by families, assisted living homes and hospitals alike.

Recent nursing home industry reports indicate that about half of all nursing home residents suffer from incontinence. The healthcare workers must physically check the diapers of the residents for wetness or odor to determine if they have had an incontinent episode. Although residents are supposed to be checked every two hours, the increasing ratio of individual residents to workers makes this task increasingly difficult. Many residents end up sitting in wet or soiled diapers or garments for prolonged periods. Even when the healthcare worker performs a check every two hours, the possibility exists that the resident may remain in undesirable condition for this length of time. This is not only uncomfortable, but can cause skin irritation and breakdown, and lead to infection and more serious health problems.

Maintaining a person in a dry, comfortable condition can be difficult to achieve on a consistent basis. The person may wet or soil themselves at various times throughout the day or night. The more frequently the person is checked, the better the care they will receive. Yet, checking for wetness or excrement is an awkward and unpleasant task for everyone involved, and

in a nursing home or hospital setting can be a relatively time consuming task. Less dedicated workers may avoid or skip this task. In addition, different healthcare workers may allow different degrees of wetness before they believe a change is required. These types of problems need to be quickly identified and addressed by the supervisors and managers of the institution.

A wide variety of wetness sensors and wetness monitoring systems have been developed to assist healthcare workers in detecting when a resident or patient is wet. Wetness sensors typically operate on chemical or electrical principals. Chemical sensors detect changes in chemical properties such as the pH or thermochromatic level of a bandage, diaper or garment. An example of such a chemical sensor is disclosed in U.S. Patent Nos. 4,583,546 to Garde and 5,197,958 and 5,389,093 to Howell. The sensor turns color when contacted by urine or excrement. When a healthcare worker sees the change in color, they know the person needs attention. A problem with chemical sensors is that they are difficult to incorporate into a system that produces an audible alarm or sends a signal to a central computer where the staff and floor supervisor are located. The administrators or other staff must duplicate the work efforts of others to watch for skin rashes and sores or identify a particular worker that is skipping some checks or simply avoiding the task altogether.

Electrical sensors and monitors have been developed to detect changes in the conductive, resistive, impedance or electromagnetic characteristics of a diaper or garment due to the presence of urine. The monitors include an electric circuit that incorporates a sensor. The monitor uses the changing electrical characteristics of the sensor responsive to a dielectric fluid such as urine to determine that the diaper or garment is wet. The monitor determines that the garment is wet when the electrical circuit exceeds a threshold level inherent to its circuit. The monitor then produces a visual or audible alarm, or sends a signal to the central computer to inform the staff

that the particular person wearing the monitor is wet and in need of attention. Examples of such sensors and monitors are discussed in U.S. Patent Nos. 3,460,123 to Bass; 4,106,001 to Mahoney; 4,356,818 to Macias; 4,796,014 to Chia; 4,977,906 to DiScipio; 5,036,859 to Brown; 5,264,830 and 5,392,032 to Kline; 5,557,263 and 5,790,036 to Fisher; 5,568,128 to Nair; 5,838,240, 5,469,145 and 5,266,928 to Johnson; 5,760,694 to Nissim and 5,903,222 to Kavarizadeh, the disclosures of which are incorporated herein.

A significant problem with conventional wetness sensors and monitoring systems is that they do not gather actual wetness data. The monitors simply determine when the sensor and circuit have exceeded a predetermined threshold limit. The monitor then sounds an alarm or sends a signal to a central computer informing the healthcare staff that the particular individual needs to be changed. Actual wetness measurement data containing large quantities of information pertaining to the person condition that could prove useful to the administration and staff to provide better care to the individuals is simply not collected or lost.

Another problem with conventional wetness monitoring systems is that their sensitivity cannot be adjusted by the administration or staff to meet the needs of a particular person. The system simply detects when the electric circuit in the monitor reaches a threshold level of wetness. If a particular person has an incontinence problem involving small releases of urine or is prone to sweat during the course of their activity throughout the day, that person's monitor may continually go off even though the person does not need immediate attention. This type of nuisance alarm may cause a healthcare worker to disregard the alarm when the person actually needs attention.

A further problem with conventional wetness sensors and monitoring systems is that they require a significant amount of power to operate properly. To minimize power consumption, the

monitor is designed to send signals as infrequently as possible. In many designs, the monitor will only send a signal to a central computer when a wetness event is detected. These types of systems have a significant drawback. The staff and supervisor do not know if a particular person is dry or if their monitor is simply malfunctioning.

A still further problem with conventional wetness sensors and monitoring systems is that the monitor provides no indication that the sensor is properly connected. Improperly trained or forgetful healthcare workers may incorrectly connect the sensor to the monitor. A worker may also be distracted or in a rush to perform other pending tasks and fail to connect the sensor and monitor correctly. Lack of training, distractions and the rush of performing a multitude of tasks can also prevent a worker from noticing that the monitor or sensor is damaged and not working properly. The resident or patient may end up wearing a soiled diaper or garment for many hours before the staff becomes aware of and corrects the problem.

A still further problem with conventional wetness sensors and monitoring systems is their excessive operating costs. Most conventional designs require the sensor to be disposed of after each use. Conductive and resistive type sensors that come in contact with the urine are typically disposed of after each use. These disposable sensors significantly increase the operating cost of the system because the sensors usually need to be replaced several times a day. A single person may require over a few thousand sensors annually. Even a relatively inexpensive sensor can result in high operating costs.

A still further problem with conventional wetness monitoring systems is that they are not designed to ensure that the individuals consistently receive proper care. The systems simply track the exact time between wetness events and garment changes. These systems inappropriately focus on the exact duration the individual is wet. Yet, many administrators of assisted living

homes and nursing homes understand that the problem is not determining whether any given wetness event is responded to in ten or fifteen minutes, but ensuring that each individual is consistently attended to in a prompt manner and not forgotten for one or two hours or an entire day.

A still further problem with conventional wetness sensors and monitoring systems is that they are difficult to put on and uncomfortable to wear. The devices are often bulky, located in inconvenient locations on the individual that make sitting, sleeping or daily activity troublesome. Many devices include mechanisms that are elaborate and difficult to use to secure the sensor and monitor or attaching them to the garment of the individual.

The present invention is intended to solve these and other problems.

SUMMARY OF THE INVENTION

The present invention relates to a wetness monitoring system that includes a data collection device that sends wetness measurement data to a central computer that detects changes in wetness measurement data caused by the presence of urine or other dielectric fluids. The data collection device includes a semi-reusable sensor and reusable data collector that are worn on a garment of the person. The data collector includes an internal power source so that the person can live a normal ambulatory life. The data collector has an electrical circuit that uses the changing resistance characteristics in the sensor to gather wetness measurement data. The data collector periodically generates and transmits a signal containing the actual wetness measurement data. The signals are coded to identify the particular data collector or person sending the signal. The data collector is programmed to conserve power by sending signals less frequently during periods when the sensor is clearly dry. Signals are sent more frequently when

the sensor is damp or a wetness event may have occurred. The central computer receives the signals containing the wetness measurement data and compares the measurement data to an adjustable wetness sensitivity level to determine if a wetness event has occurred. When the central computer determines that a wetness event has occurred, the computer displays the name of the particular person wearing the data collector and the approximate time that the wetness event occurred. The system then pages an appropriate healthcare worker to inform them that the particular individual needs attention and tracks the approximate response times to ensure that the patient is continuously receiving prompt care.

One advantage of the present wetness monitoring system is that it gathers and monitors actual wetness measurement data. The central computer monitors the actual measurement data to determine when several consecutive measurements exceed a sensitivity limit that is preselected for that particular individual to identify when a wetness event occurs. The central computer then pages the appropriate healthcare workers to inform them that the particular individual needs attention. The actual wetness data is saved and used to track approximate wetness durations and ensure that the individual is consistently receiving proper care.

Another advantage of the present wetness monitoring system is that a supervisor can easily adjust the sensitivity level of each person being monitored to ensure that the system meets the needs of each individual being monitored by the system. The supervisor can quickly and easily select one of a variety of sensitivity levels for each individual. If a particular person has an incontinence problem involving small releases of urine or is prone to sweat at particular times during their course of activity throughout the day, the sensitivity level in the central computer can be adjusted for that individual so that it will reliably determine that a wetness event has

occurred when the person actually needs attention. Nuisance alarms are minimized so that the healthcare workers do not disregard or avoid responding to a page.

A further advantage of the present wetness monitoring system is that the data collector includes a power conservation circuit that minimizes the power consumption during periods when the sensor is relatively dry. The data collector is designed to send signals at periodic intervals. Signals are sent relatively infrequently when the sensor is clearly dry, and are more frequently when the sensor is damp or a wetness event may have occurred. The data collector sends signals periodically throughout the day to a central computer whether or not a wetness event is detected by the central computer. The staff and floor supervisors are informed that each data collection device is operating properly even if the individual remains dry for a relatively long period of time.

A still further advantage of the present wetness monitoring system is that the data collector indicates when it is properly connected to the sensor. A visible indicator light in the data collector flashes when the sensor is correctly secured to its data collector so that the wetness measurement circuit is working properly. The connection indicator light flashes several times to ensure that the worker sees the light even if they are momentarily distracted or in a rush to perform other pending tasks. This indication light helps minimize adverse connection of the sensor to the data collector that can arise due to lack of training, distractions and the rush the workers may experience when they are performing a multitude of tasks. This feature also helps the workers identify defective sensors or data collectors that become damaged during use.

A still further advantage of the present wetness monitoring system is that operating costs are reduced. The sensor is designed to be washed up to four times and used five times before disposal. The backing layer of the sensor is made of a durable, shrink and tear resistant material.

The two spaced, conductive sensor strips are uniformly glued or otherwise secured throughout the entire top surface of the backing layer. Similarly, the absorbent layer is uniformly secured throughout the entire top surfaces of the backing layer and sensor strips. The selected materials and sensor design forms an integral sensor that maintains its shape and integrity for a limited number of uses and wash cycles. This reusability dramatically reduces the annual operating cost of the system. A person may only require a few hundred sensors on an annual basis instead of a few thousand.

A still further advantage of the present wetness monitoring system is that the sensor is easily positioned over and secured to the housing of the data collector. Two posts extend from the housing to receive one set of two corresponding holes in the sensor. The posts and holes position the sensor so that each conductive sensor strip is aligned with a contact of the data collector. A U-shaped clamp is then placed over the sensor and around the sides of the housing to hold the sensor in place. The clamp compresses the sensor against the contacts, so that the contacts pierce the backing or absorption layer and electrically engage their respective conductive strips in the sensor. This simple securement mechanism is easy to use and helps prevent operating errors when performing this rather repetitive task.

A still further advantage of the present wetness monitoring system invention is that each time the sensor is clipped to the housing of the data collector, the sensor is marked to indicate how many times that sensor has been used. The sensor is typically provided with five sets of holes. Each time the sensor is clipped to the housing, the contacts pierce or otherwise mark the sensor. These marks or indicia are located next to the set of holes that were just used to position the sensor on the housing. When the sensor is removed, these marks are easily visible to the healthcare workers. The pierce marks remain visible after the sensor is washed several times.

Each time the sensor is connected to the housing of the data collector, an unmarked set of holes is inserted into the posts of the housing. The healthcare workers can use the marks and holes to easily track or otherwise determine how many times the sensor has been used. The sensor is disposed of when each of the five sets of holes has a corresponding mark.

A still further advantage of the present wetness monitoring system is that it provides a data collector designed to be reused thousands of times with minimal or no servicing. The housing hermetically seals the electronic components inside its compartment so that they are not exposed to humidity or moisture. The compartment cannot be opened without breaking the housing, which ensures that the components remain in a sterile moisture free environment throughout the life of the data collector. The electrical contacts that extend from the housing are also protected by a sensor fastening member or clamp. The housing and clamp are designed to ensure that the contacts are not bent when the clamp secures the sensor to the housing and in electrical engagement with the contacts. The housing includes a pair of alignment posts that ensure the contacts are properly aligned with the sensor strip and clamp when the clamp is secured. The clamp and posts also lock the sensor strip in place so that the contacts are not bent should a person inadvertently attempt to pull the sensor strip out of engagement with the data collector without first releasing the clamp.

A still further advantage of the present wetness monitoring system is that it focuses on ensuring that every individual being monitored consistently receives proper care. The system does not focus on tracking the exact time between a wetness event and a garment change. Instead, the system is designed to meet the overall management needs of assisted living home and nursing home administrators to assure that each individual is consistently attended to in a prompt manner and not continuously forgotten for several hours or an entire day.

A still further advantage of the present wetness monitoring system is that the sensor and data collector components are relatively easy to put on and comfortable to wear. The sensor is soft to the touch and very flexible to conform to the contours of the body of the individual. The data collector is relatively small and light weight, and designed to be located near the abdomen of the individual so that it is not readily noticed when walking, running, sitting or reclining.

Other aspects and advantages of the invention will become apparent upon making reference to the specification, claims and drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1a is a perspective view of an assisted living home installed with the present wetness monitoring and detection system invention where the residents are wearing data collection devices that collect wetness measurement data and send coded signals containing that measurement data to a central computer that determines when a wetness event has occurred, displays this event on a computer monitor and pages an appropriate healthcare worker.

Figure 1b is an overhead view of the assisted living home of **Figure 1a**.

Figure 2 is a view of an individual wearing a garment and the wetness measurement data collection device formed by a sensor and a data collector.

Figure 3 is a perspective view of the sensor strip having an absorbent layer, two spaced conductive strips, and a backing layer, and one end of the sensor strip having five sets of holes, two sets of holes being marked to indicate that the sensor has been used twice.

Figure 4 is a cross-sectional view of **Figure 3** taken along lines 4-4 showing one of the conductive strips sandwiched and enclosed between the absorbent pad and backing layer.

Figure 5 is a perspective view showing the sensor strip secured to the garment via a positioning sheet.

Figure 6 is a top, perspective view of the data collector with the sensor clamp in a release position and rotated to show its recesses on its inside surface.

Figure 7 is a side, cross-sectional view of the data collector with its sensor clamp in a secure position and showing its internal electrical components.

Figure 8 is a bottom, perspective view of the data collector showing its garment clip.

Figure 9 is a perspective view showing the sensing strip aligned over the housing of the data collector with one set of holes receiving the posts and each conductive strip being pierced by one set of barbed contacts, and showing the sensor clip in an aligned position just prior to fastening the sensor strip to the housing.

Figure 10a is a side, partial cross-sectional view showing the data collector fastened to a garment by the garment clip, the sensor strip fastened to the data collector by the sensor clamp, and the sensor strip looped under the monitor, over the garment and down along an inside surface of the garment.

Figure 10b is a top, cross-sectional view of the data collector of **Figure 10a**.

Figure 11 is an electrical schematic of the data collector.

Figure 12a is a flow chart showing much of the programming for the data collector.

Figure 12b is a flow chart showing the remainder of the programming of **Figure 12a**.

Figure 13 is a chart showing the wetness measurement data gathered by the data collector every 35 seconds and transmitted via signals to the central computer system at 25 minute intervals when the sensor is clearly dry and at 140 second intervals when the sensor is damp or a potential wetness event is occurring.

Figure 14 is a table showing the wetness or resistance measurement data gathered by the data collector for a particular person and stored in the memory of the central computer system.

Figure 15 is a table showing a report generated by the central computer system identifying several particular individuals using the system and the approximate times of their wetness and garment change events.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

While this invention could take on a variety of different embodiments and forms, the drawings show and the specification describes a preferred embodiment. However, it should be understood that the drawings and specification are to be considered an exemplification of the principles of the invention, and are not intended to limit the broad aspects of the invention to the embodiment illustrated and discussed.

Many individuals 5 desire or need assistance from healthcare workers 7 such as nurses, nurses aids, nutritionists, cooks, doctors, etc. These individuals live in assisted living or nursing homes 10, and are frequently afflicted with bladder control problems that hinder their ability to notice when their bladder is full or exert the control needed to hold their bladder until they are able to use a bathroom. The consequence of this affliction is that the individual 5 ends up wetting his or her undergarment or diaper 15 worn around the waist and groin of the individual. Above and beyond the embarrassing and awkward situation this affliction creates, this affliction presents a personal hygiene problem that can lead to the irritation and breakdown of the skin when left unattended for a significant amount of time.

The present invention pertains to a wetness monitoring system that is generally referred to by reference number 20. As shown in **Figures 1a, 1b and 2**, the wetness monitoring system

20 includes a wetness measurement collection device 25 formed by a semi-reusable sensor 30 and a reusable data collector 100. The data collector 100 is equipped with a transmitter that periodically sends the measurement data to a central computer system 300 to determine when a wetness event occurs. As discussed below, the data collection device 25 is secured to or worn on the garment 15 of the individual. Although the wetness sensing system 20 is shown and described as being used for a number of individuals 5, it should be understood that the system could be adapted for one or two individuals in a single family home environment without departing from the broad aspects of the invention.

As shown in **Figures 3 and 4**, the sensor or sensing strip 30 has upper and lower surfaces 34 and 35, substantially parallel side edges 36 and 37 and ends 38 and 39. The sensing strip 30 includes an absorbent pad 40, a backing sheet 50 and two spaced, substantially parallel, conductive strips 61 and 62. The absorbent pad 40 is designed to absorb a liquid or an amount of wetness. The conductive strips 61 and 62 are spaced apart a relatively constant or uniform distance of about 1.5 inches down the length of the sensor 30 to produce an amount of resistance between the conductive strips. The sensor 30 produces an actual wetness value indicative of the amount of wetness absorbed by the absorbent material 40 between the conductive strips 61 and 62 at a given point in time, as discussed below.

The absorbent pad 40 is formed by a sheet of soft, flexible, highly absorbent material that does not irritate or sensitize human skin, and is preferably a polyester product manufactured by Avery as product 5322P. The absorbent pad 40 is highly porous, breathable, and freely passes air and moisture. The pad 40 includes top and bottom surfaces 44 and 45. The backing sheet 50 is a paper thin, highly flexible, shrink resistant, and tear resistant material, and is preferably a polyethylene product manufactured by DuPont as Tyvek® 1443R. The backing sheet includes

top and bottom surfaces 54 and 55. The absorbent pad 40 and backing sheet 50 are substantially nonconductive when free from sweat, tap water, urine and other conductive materials.

Each conductive sensor strips 61 and 62 is formed by a strip of flexible, corrosive resistant, conductive material, such as a woven nylon or polyester fabric coated with copper or nickel manufactured by Monsanto as Flectron™. Each strip 61 and 62 has top and bottom surfaces 64 and 65 and inner and outer edges 66 and 67. Each strip 61 and 62 has a width of about 1/4 of an inch between edges 66 and 67. The outer edge 67 of each strip 61 and 62 is about 1/4 inch from its respective edge 36 or 37 of the sensor 30.

The sensor strips 30 are manufactured in roll form by bonding the absorbent pad 40, backing layer 50 and conductive strips 61 and 62 together to form an integral strip. During manufacture, a first adhesive coating (not shown) is applied across the entire bottom surface 45 of the absorbent pad 40. The conductive strips 61 and 62 are then rolled onto or otherwise laid against the adhesive on the bottom surface 45 so that the top surface 64 of each strip engages the bottom surface of the pad 40. The adhesive firmly secures each strip 61 and 62 to the pad 40. A second adhesive coating (not shown) is applied across the entire surface 54 of the backing layer 50, except for about an 1/8 of an inch portions extending along its longitudinal edges. The first and second adhesive coatings combine to cover the entire top and bottom surfaces 64 and 65 of conductive strips 61 and 62. The adhesive is preferably an acrylic copolymer that is not irritating or sensitizing to humans.

The backing layer 50 is rolled onto or otherwise laid against the pad 40 and strips 61 and 62 so that the top surface 54 of the backing layer engages the bottom surfaces 45 and 65 of the pad 40 and strips 61 and 62. The adhesive coatings firmly secure the backing layer 50 to the pad 40 and strips 61 and 62. The conductive strips 61 and 62 are sandwiched between and enclosed

or encased by the pad 40 and backing layer 50. The backing layer 50 is preferably about $1/32$ of an inch wider than the pad 40 so that the adhesive layer applied to the pad is completely covered by the backing layer 50 during the manufacturing process. The pad 40, backing layer 50 and conductive strips 61 and 62 are bonded or otherwise secured together to form a roll of the integral sensor strip 30. This roll is then cut into strips 30 having a length of 24 inches. The individual sensor strips 30 have a width of about 2.5 inches, and a thickness of about 0.01 of an inch. It should be understood that the sensor strips 30 can be manufactured to different lengths and widths to accommodate different size individuals, such as adults and children.

Ten holes 80 are punched through each sensor strip 30. The holes 80 are located near the end 38 of the sensor 30 to be secured to the data collector 100, as discussed below. Each hole 80 has a diameter of about $3/16$ of an inch and extends completely through the pad 40 and backing layer 50, but does not engage the conductive strips 61 and 62 which remain enclosed between the pad and backing layer. Half of the holes 81 are located in a row extending along one side 36 of the strip 30 near the inside edge 66 of conductive strip 61, and half of the holes 82 are located in a row extending along the other side 37 of the strip near the inside edge of the other conductive strip 62. The holes 80 are arranged to form five sets of holes 85-89. Each set 85-89 includes one hole 81 near conductive strip 61 and one hole 82 near conductive strip 62. Although the sensor strip 30 is shown and described as having five sets of two holes for a total of ten holes, it should be understood that the sensor could have fewer or more sets of holes without departing from the broad aspects of the invention. It should also be understood that each set of holes could be formed by more than two holes or could be a single hole without departing from the broad aspects of the invention.

As shown in **Figure 5**, the sensor 30 is laid on the inside surface of the garment 15 with the absorbent pad 40 preferably facing toward the skin of the person 5 and the backing layer 50 facing the garment 15. However, it should be understood that the collecting device 25 will operate effectively if the backing layer 50 faces the skin of the person 5. A positioning sheet 90 can be used to maintain the sensor 30 in proper alignment on the garment 15 during use. The positioning sheet 90 also acts as a shield for the sensor strip 30 to help keep solid waste off of or adhering to the sensor strip during use. The positioning sheet 90 has two opposed ends 92 and 93 that define its length and two opposed parallel edges 94 and 95 that define its width. The width of the positioning sheet 90 is larger than the width of the sensor strip 30. The positioning sheet 90 is placed over the sensor strip 30 so that the outer edges 94 and 95 straddle or extend beyond the edges 36 and 37 of the sensor strip 30. Two adhesive coating strips 96 and 97 are applied to a bottom surface of the positioning sheet 90. Each coating strip 96 and 97 extends the length of the sheet 90 along one of its outer edges 94 and 95. These adhesive coatings 96 and 97 secure the positioning sheet 90 to the garment 15. The sensor strip 30 is maintained between the edges 94 and 95 of the positioning sheet 90 to ensure that the sensor is maintained against a location of potential wetness such as the groin area of the individual 5 during use. The positioning sheet 90 is a very thin sheet of liquid permeable material that is not irritating or sensitizing to humans.

The data collector 100 is relatively small and compact as shown in **Figures 6-9**. The outer margins of the data collector 100 are generally defined by its housing 102. The housing 102 includes a shell 104 that forms the front wall 105 and sidewalls 106-109 of the housing, and a lid 110 that forms the back wall 112 of the housing. The corners and edges of the shell 104 are rounded for comfort. The lid 110 is relatively flat. The shell 104 and lid 110 are made of a rigid,

shatter-proof material such as a polycarbonate plastic. The shell 104 and lid 110 are joined together to form a water tight, interior chamber or enclosure 115 that contains and protects various electrical components inside. The housing 102 preferably has a height of about 1.25 inches from front 105 to back 112, a length of about 4 inches from side 106 to side 107, and a width of about 2 inches from side 108 to side 109. The housing 102 is preferably transparent to allow the healthcare workers 7 to see an indicator light sealed inside the chamber 115, as discussed below. The sidewalls 106-109 of the shell 104 extend below the bottom wall 112 of the lid 110 to form a lip 116 extending around the lid.

The outer surface of the shell 104 has a continuous channel 120 extending into the front wall 105 and sidewalls 106 and 107, as best shown in **Figure 6**. The channel 120 is bounded by brims 121 and 122 and has a width of about one inch and as a depth of about 1/8 of an inch. Two posts 125 and 126 project perpendicularly from the front wall 105 and extend into the channel 120. The posts 125 and 126 are an integral part of the shell 104 and are spaced about one inch apart, each post being symmetrically spaced about a half inch from the center of the shell. Two platforms 128 and 129 also project from the front wall 105 and extend into the channel 120. The platforms 128 and 129 are an integral part of the shell 104 and are located just outside of the posts 125 and 126. The platforms 128 and 129 are spaced about 1.5 apart to coincide with the distance between conductive strips 61 and 62.

Conductive contacts PC1-PC4 are embedded in and extend completely through the front wall 105 of the housing 102. The contacts PC1-PC4 are preferably made of beryllium copper. The outer ends 135 of the contacts PC1-PC4 are barbed. Each barb has a relatively sharp point or tip. A first set of spaced contacts PC1 and PC2 project out from platform 128, and a second set of spaced contacts PC3 and PC4 project out from platform 129. The contacts PC1-PC4

extend perpendicular to the front wall 105 and parallel to the posts 125 and 126. The posts 125 and 126, platforms 128 and 129, and contacts PC1-PC4 extend out of the channel 120 slightly beyond the outer surface of the front wall 105. The posts 125 and 126 preferably extend slightly farther out than the tips of the barbed contacts PC1-PC4.

The housing includes a fastener or clamp 140 to removably secure the sensor strip 30 to the data collector 100. The clamp 140 has a U-shape with a middle portion 141 and two perpendicular legs 142 and 143. Each leg 142 and 143 has a free end with an inwardly extending flange 144. The clamp 140 has inside and outside surfaces 146 and 147, and side edges 148 and 149. The clamp 140 is sized and shaped to be relatively smoothly or flushly received by channel 120. Along the length of each side edge 148 and 149 of the clamp 140 is a rim 151 or 152. The rims 151 and 152 have a thickness of about $1/8$ of an inch, or roughly the same as the depth of the channel 120. The width of the clamp 140 is about $31/32$ of an inch, just slightly less than the width of the channel 120. The length of the clamp is about 3.25 inches, or roughly the same as the length as the shell 104. The clamp 140 is made of a resilient plastic that allows it to be snap fit into the channel 120 of the housing 102. The length of the legs 142 and 143 is such that each flange 144 snap fits around and abuts against the lid 110 when the clamp 140 is inserted into the channel 120. This snap fit holds the clamp 140 snug inside the channel 120 and secures it to the housing 102. Although a clamp 140 is shown and described to secure the sensor to the data collector 100, it should be understood that other types of fasteners could be used without departing from the broad aspects of the invention.

The inside surface 146 of the clamp 140 has two symmetrical, slightly thicker, raised areas 160, as best shown in Figure 6. Each raised area 160 has two sets of slit recesses 161 and 162 or 163 and 164. The slit recesses 161 and 162 receive the tips of the barbed contacts PC1

and PC2 when the clamp is secured to the housing 102. The slit recesses 163 and 164 receive the tips of the barbed contacts PC3 and PC4. Each raised area 160 also has a pair of round recesses 165 and 166 for receiving the top of the posts 125 and 126. The outer ends of the posts 125 and 126 are slightly rounded to help them align with and slide into their respective recess 165 or 166. As stated above, the posts 125 and 126 preferably extend slightly further out than the ends of the barbed contacts PC1-PC4,

The posts 125 and 126 act as a guide to ensure that the barbed tips 135 of the contacts PC1-PC4 are properly aligned with and received by their recesses 161-164. The slightly longer posts 125 and 126 engage the raised area 160 of the clamp 140 before the barbed tips 135 to help ensure that the tips are not compressed against, bent or otherwise damaged by the inside surface 146 of the clamp 140 when the clamp is snap fit onto the housing 102. When the clamp 140 is secured to the housing 102, the outer ends of the posts 125 and 126 bottom out in their respective recesses 165 and 166, and prevent the barbed tips 135 of contacts PC1-PC4 from bottoming out in their recesses 161-164 to provide additional protection to the barbed tips.

As shown in **Figure 9**, the sensor strip 30 is secured to the data collector 100 by removing the clamp 140 to a release position and placing the strip over the front 105 of the housing 102. The sensor strip 30 is then aligned with the data collector 100 by laying the sensor flat over the front wall 105 and perpendicular to channel 120, and inserting posts 125 and 126 through one set of holes 85, 86, 87, 88 or 89. This aligns each conductive strip 61 and 62 over one of the two platforms 128 and 129 and sets of barbed contacts PC1 and PC2 or PC3 and PC4. The absorbent pad 40 is preferably facing down against the front 105 of the housing 102 with the backing layer 50 facing away from the housing. If desired, the healthcare worker 7 can press against an area of the backing layer 50 directly over the barbed contacts PC1-PC4 so that each

barbed contact pierces into the pad 40 to help hold the sensor strip 30 in place while aligning and securing the clamp 140 in place. Although the sensor 30 is shown and described as laying with the pad 40 facing the channel 120 and the backing layer 50 facing the clamp 140, it should be understood that proper securement and electrical engagement can be achieved when the sensor is flipped over with the backing layer facing the channel.

Once the sensor 30 is properly aligned over the housing 102, the clamp 140 is used to lock the sensor in place. The clamp 140 is moved to its aligned position shown in **Figure 9**. The side edges 148 and 149 of the clamp 140 are parallel to the channel 120 so that legs 142 and 143 enter the slots formed by the channel in sidewalls 106 and 107. The middle 141 of the clamp 140 is then pushed toward and down into the channel 120. The legs 142 and 143 slide along the portion of the channel formed in the sidewalls 106 and 107 until the flanges 144 snap fits around the lid 110 and the posts 125 and 126 bottom out in their recesses 165 and 166. This snap fit secures the clamp 140 into its secure position as shown in **Figures 7, 8 and 10**, and locks the sensor 30 in place to the housing 102.

The snap fit of the clamp 140 secures and locks the sensor 30 to the housing 102. The sensor strip 30 is intertwined around and compressed between the brims 121 and 122 of the channel 120 and the rims 151 and 152 of the clamp 140. Posts 125 and 126 also extend through one of the sets of holes 85-89 and into their respective recesses 165 and 166 in the clamp 140. The inside surface 146 of the clamp 140 presses against the backing layer 50 of the sensor 30 to maintain the barbed contacts PC1-PC4 in their pierced orientation through the pad 40 and in electrical engagement with their respective conductive strips 61 or 62. The barb contacts PC1-PC4 either pierce entirely or partially through the sensor 30. When the contacts PC1-PC4 pierce entirely through the sensor 30, the barbs pierce the backing layer 50 and enter their respective

recesses 161-164. When the contacts PC1-PC4 only partially pierce the sensor 30, the contacts deform the backing layer by pushing or otherwise forcing it into the slit recess 161-164. In either event, the sensor 30, and particularly the backing layer 50, becomes visibly and substantially permanently or otherwise lastingly deformed or marked as a result of being secured to the data collector 100 by the clamp 140. The sensor 30 remains visibly marked when the clamp 140 and sensor are removed from the data collector 100 and the sensor is cleaned, as discussed below.

The wetness data collecting device 25 formed by the joined and electrically connected sensor 30 and data collector 100 is now ready to be placed on and secured to the garment 15 of the individual 5. The data collector 100 is removably secured to the garment 15 of the individual 5 by a belt clip 180. The belt clip 180 is made of a resilient strand 181 of nonconductive and non-corrosive material, such as music wire with a black zinc dichromate coating. As best shown in Figure 8, the clip 180 has two U-shaped legs 182 and a single U-shaped middle or outer portion 183. Each leg 182 lays flat against the outer surface of the back wall 112 of the lid 110, and has first and second ends 184 and 185 that are secured to the back wall via L-shaped mounting brackets 186 and 187. The brackets 186 and 187 extend from the outer surface of the back wall 112 and are an integral part of the lid 110. The two brackets 186 closest the sidewall 108 have an open end facing that sidewall 108. The two opposed brackets 187 closest the sidewall 109 have an open end facing that sidewall 119. The diameter of the metal strand forming the clip 180 is slightly larger than the openings of the brackets 186 and 187 so that the ends of the legs 182 are snugly received by the openings in the brackets. The U-shape of the legs 182, the orientation of the opposed facing brackets 186 and 187, and the relative sizes of the legs and open ends of the brackets combine to secure the clip 180 to the lid 110. The middle or outer portion 183 of the clip 180 is formed in a folded back position to extend over the legs 182.

The outer portion 183 is biased so that its top 189 presses or pinches down on the legs 182, brackets 186 or back wall 112 of the lid 110. Although a clip 180 is shown and described to secure the data collector 100 to the garment 15, it should be understood that other types of fasteners could be used without departing from the broad aspects of the invention.

The data collector 100 is preferably secured to the garment 15 of the individual 5 by facing the back wall 112 towards the individual with the top or open end 189 of the clip 180 facing down, as shown in Figure 10a and 10b. The top edge of the garment 15 is then pushed or otherwise inserted between the top 189 of the outer portion 183 of the clip 180 and its legs 182. The insertion of the garment 15 causes the clip 180 to bend where the legs 182 and outer portion 183 intersect, and moves the top 189 of the outer portion away from the legs. The resilient nature of the clip 180 biases the outer portion 183 back toward the legs 182. This biasing action pinches the garment 15 between the outer portion 183 and the legs 182, brackets 186 or back wall 112 of the lid 110, and secures the data collector 100 to the garment and the individual 5. As noted above, a positioning sheet or shield 90 can be used to maintain the sensor strip 30 in a desired position on the garment 15.

The data collection device 25 is easily removed from the garment 15 of the individual 5 by simply releasing the garment from the clip 180. The sensor strip 30 is removed from between the positioning sheet or shield 90 and the garment 15 by pulling its end 38. The sensor 30 is removed from the data collector 100 by removing the clamp 140 and pulling or otherwise removing the sensor 30 out of its pierced engagement with the barbed contacts PC1-PC4. As noted above, the piercing or compressing engagement of the barbed contacts PC1-PC4 leaves a number of visible marks 190 in the sensor 30. The marks 190 are formed next to the selected set 85, 86, 87, 88 or 89 of holes 80 through which the posts 125 and 126 passed when the sensor was

secured in place by the clamp 140. The marks 190 are formed by each of the two holes 81 and 82 forming the selected set of holes.

The marks or indicia 190 in the sensor 30 remain even after the sensor has been washed or otherwise sanitized and reused several times. Each time the sensor strip 30 is used, the posts 125 and 126 are aligned with a different, previously unused and thus unmarked, set of holes 85-89. The healthcare worker 7 can track or otherwise determine how many times a sensor 30 has been used by noting how many sets of holes 85-89 have a mark 190 by them. For example, **Figure 3** shows a sensor that has been used twice as indicated by the marks 190 by two sets of holes 85 and 86. The sensor 30 is designed to have a life span that will withstand four washings so that the sensor can be used five times. When marks 190 appear by each of the five sets of holes 85-89, the healthcare worker 7 is instructed to dispose of the sensor or otherwise remove it from further use.

The data collector 100 has an electrical circuitry 200 shown in **Figure 11**. The circuitry 200 includes components such as a circuit board 210, a processor 220 with an associated memory 225 and clock 227, a power source such as a battery 230, and a communication device such as a transmitter 240. As noted above, these components are sealed inside the chamber 115 of the housing 102 and firmly secured to the shell 104 as shown in **Figure 7**. The circuitry 200 also includes the contacts PC1-PC4 embedded in the housing 102 and their exposed barbed tips 135. The processor or microcontroller 220 is preferably sized for mounting on the circuit board 210 with a 14-pin SOIC footprint, and is protected by a watchdog timer. The processor 220 is programmed as in **Figures 12a** and **12b**. The data collector 100 has an approximate battery life of one year, assuming a 63% duty cycle or 15 hours of use per day. The data collector 100 is not

intended to be serviceable, and the battery 230 is not intended to be replaceable. At end of its service life, the data collector 100 is simply thrown away or otherwise taken out of service.

The circuitry 200 includes a sensor detection circuit 250 that allows the processor 220 to determine when the sensor 30 is properly attached to the data collector 100. As shown in **Figure 11**, the sensor detection circuit 250 includes ports RC1 and RC3, contacts PC3 and PC4 and resistor R1. The processor 220 periodically applies a 3-volt potential or signal S1 to port RC3 every few seconds (e.g., about every 2-3 seconds). When the sensor 30 is properly attached to the data collector 100, contacts PC3 and PC4 are both in electrical communication with conductive strip 62. The 3-volt signal travels from port RC3 to contact PC4, from contact PC4 through conductive strip 62 and to contact PC3, and from contact PC3 back to the processor via resistor R1 and port RC1. When the processor 220 senses the signal S1 at port RC1, the processor determines that a sensor 30 is properly attached to the data collector 100. The processor 220 is programmed to continue periodically applying the signal S1 at port RC3 and to continue looking for the signal at port RC1 to ensure that the sensor 30 remains properly attached to the data collector 100.

The processor 220 is programmed to use the sensor detection circuit 250 to determine when a new or clean sensor 30 is attached to the data collector 100. Before a new sensor 30 can be attached, the used, wet, damp, or otherwise soiled sensor must be removed. When the used sensor 30 is removed, no sensor is attached to the data collector 100 and the processor 220 will not receive signal S1 at port RC1 even though the signal is still being sent via port RC3. As indicated in **Figures 12a and 12b**, the processor 220 is programmed to set a flag F1 in the absence of receiving signal S1 at port RC1. This flag F1 is used in the programming to indicate that no sensor 30 is present or attached to the data collector 100. When the flag F1 is set and a

new, dry or otherwise clean sensor 30 is secured to the data collector 100 in a proper manner, the processor 220 begins receiving signals S1 at port RC1 and is programmed to determine that a new sensor 30 has just been attached to the data collector. The processor 220 then sets the flag F1 in its programming to indicate that the new sensor 30 is attached to the data collector 100, and activates an indicator light 245 inside the chamber 115 of the data collector 100 as indicated in **Figure 12a**. The indicator light 245 flashes on and off about five times, for about ten seconds, to give the healthcare worker 7 time to observe the light. This flashing indicator light 245 informs the healthcare worker that the sensor 30 is properly attached to the data collector 100.

The circuitry 200 also includes a wetness measurement circuit 255 that allows the data collector 100 to gather wetness measurement data corresponding to the actual wetness value of the sensor as shown in **Figure 13**. The wetness measurement circuit 255 includes ports RC2 and RC3, contacts PC1, PC2 and PC4, capacitor C3 and resistor R2. The processor 220 is programmed to activate the wetness measurement circuit 255 and begin gathering wetness measurement data when a dry sensor 30 is properly secured to the data collector 100. The wetness measurement circuit 255 uses the same 3-volt potential applied to port RC3 used to generate the signal S1 for the sensor detection circuit. As shown in **Figure 11**, a separate signal S2 branches off from signal S1 at PC4. Signal S2 travels from PC4 and down the length of conductive strip 62. Depending on the degree of wetness of the sensor 30, a portion of the signal S2 crosses from strip 62 to strip 61. The signal S2 then travels from strip 61 to contacts PC1 and PC2, and back to the processor 220 via port RC2. The return path takes the signal S2 by capacitor C3. The signal S2 is consumed by and will not pass capacitor C3 until the capacitor is charged to a predetermined level by the signal. Charging the capacitor C3 takes time and delays the receipt of the signal S2 at port RC2. The processor 220 uses its internal clock 227 to measure

the time the signal S2 takes to charge capacitor C3 to its predetermined level and pass on to port RC2. The processor 220 looks for signal S2 at port RC2 about every 35 seconds (2.3 seconds x 15).

When no sensor or a completely dry sensor 30 is attached to the data collector 100, capacitor C3 does not charge to its predetermined level because there is virtually an infinite resistance between the conductive strips 61 and 62, and no signal S2 will be received at port RC2. The processor 220 is programmed to configure this uncharged time measurement to correspond to a resistance of 4,200,000 ohms. When the sensor 30 is dampened or wetted by sweat, urine, tap water, or another dielectric material or fluid, the resistance between the conductive strips 61 and 62 decreases. This decrease in resistance allows a portion of the signal S2 to travel to and charge capacitor C3. The processor 220 measures the time between when the signal S2 is sent from port RC3 to the time the signal is received at port RC2. As noted above, the difference in time is the time the signal S2 takes to charge capacitor C3. The time measurements are correlated to resistance or wetness measurement data. Figure 13 shows a continuous series of wetness measurement data obtained by the data collector 25 every 35 seconds.

The data compiling processor 220 compares each time or wetness measurement data to a predetermined power conservation value. In the preferred embodiment, this conservation value is set at 5,000 ohms, or the time it would take the signal S2 to charge capacitor C3 if a 5,000 ohm resistor were placed between the conductive strips 61 and 62. Test observations of the system 20 indicate that measurements of 5,000 ohms or above are indicative of a sensor 30 that is clearly dry to the touch, and measurements of about 3,000 ohms are indicative of a sensor that is just becoming noticeably damp to the touch. The processor 220 saves each resistance measurement in

its memory 225. However, only the four most recent resistance measurement data are maintained in the memory 225. The older measurement data are written over or otherwise discarded. The wetness measurement circuit 255 determines the resistance of the sensor 30 to within 10% from 1,000 ohms to 1,000,000 ohms.

The data collection device 25 uses the transmitter 240 to periodically generate and transmit wetness measurement data signals S3 to the central computer 300, as shown in Figure 13. The transmitter 240 preferably produces signals S3 having standard NRZ data, positive logic, one start bit, 8 data bits, and a stop bit. The data rate is preferably 9600 baud. The transmitter 240 is preferably an Inovonics serial transmitter model FA240XS. A unique identification number or code is programmed into each transmitter 240 and sent with each signal S3. The transmitter 240 is firmly secured to the lid 110 of the housing 102 as shown in Figure 7.

The transmitter 240 sends signals S3 containing resistance or wetness measurement data whether the sensor 30 is dry, damp or wet as best shown in Figure 13. To preserve power and the life expectancy of the battery 230 and data collector 100, wetness measurement data is sent less frequently or at a slower rate when the sensor 30 is relatively dry, and more frequently or a faster rate when the sensor is damp or wetted to a significant degree. When the resistance or wetness measurement data remains above the 5,000 ohm power conservation level, the processor 220 is programmed to measure resistance data about every 35 seconds and transmit data about every 25 minutes. Although about 50 measurements have been taken in this 25 minute period, only the four most recent resistance measurements remain in the memory 225 and are sent to the central computer 300. When the wetness measurement data falls below or otherwise exceeds the 5,000 ohm power conservation level, the processor 220 is programmed to continue measuring resistance data about every 35 seconds, but transmit that data about every 140 seconds (4 x 35).

Each of the four wetness measurement data obtained by the data collector 100 and stored in its memory during this 140 second period are sent to the central computer 300, so that every resistance measurement indicative of a damp or significantly wet sensor 30 is sent to the central computer. As noted above, each signal S3 sent by the transmitter 240 includes the unique identification number for the transmitter 240, and thus the corresponding individual 5 wearing the device. Monitoring systems 20 for larger assisted living and nursing homes 10 utilize transceivers 260 located at convenient places about the assisted living or nursing home. These transceivers 260 receive and boost the signals S3 from the transmitters 240, and retransmit them to the central computer station 300.

The central computer station 300 is typically located at a central station or nursing station, as shown in **Figures 1a** and **1b**. The control station 300 includes a processor 310, memory 312, monitor 315, printer 320, receiver 340 and base pager station 350. The control processor 310 is programmed with a password to limit access to authorized administrators and healthcare workers. The receiver 340 is compatible with the transmitter 240 for receiving signals S3, and is preferably an Inovonics serial receiver model FA403. The base pager station or paging transmitter 350 is preferably an in house paging station such as the Scope Telepath 450. The control processor 310 and its accessories are backed up by an uninterruptible power supply.

The control processor 310 analyzes the wetness or resistance measurement data received by receiver 340 to determine whether or not a wetness event or a change event has occurred. The processor 310 is programmed with an adjustable wetness value or threshold level that is considered to be indicative of a wetness event. The programming allows an administrator at the nursing station to select this threshold level from one of several wetness sensitivity levels for

each individual 5. A different sensitivity level can be selected for each individual 5 using the monitoring and detection system 20.

The processor 310 is programmed to allow the administrator or nurse to select either a "high," "medium" or "low" sensitivity level for each individual. The "high" sensitivity level will determine that a wetness event has occurred when the processor 310 receives five consecutive resistance measurements of 3,000 ohms or less. The "medium" or "medium" sensitivity level will determine that a wetness event has occurred when the processor 310 receives five consecutive resistance measurements of 2,000 ohms or less. The "low" sensitivity level will determine that a wetness event has occurred when the processor 310 receives five consecutive resistance measurements of 1,000 ohms or less. The "high" sensitivity level setting will cause the processor 310 to determine that a wetness event has occurred when the sensor 30 is slightly wet or has a low degree of wetness. The "middle" sensitivity level setting will cause the processor 310 to determine that a wetness event has occurred when the sensor 30 is mildly wet or has a middle degree of wetness. The "low" setting will only indicate a wetness event when the sensor is very wet or has a high degree of wetness. The computer system 300 will indicate that a wetness event has occurred when five consecutive resistance measurement data are received below the selected threshold or sensitivity level for a given individual. Although the system has been described to include three sensitivity levels, it should be understood that the system could have two sensitivity levels or an infinite number of sensitivity levels without departing from the broad aspects of the invention. Given that in the preferred embodiment each data signal S3 contains four wetness measurement data, which is fewer than the five consecutive wetness data measurements needed by the central computer system 300 to determine that a wetness event has occurred, at least two signals S3 are needed to determine that a wetness event has occurred.

The central computer system 300 has the capability to use a time derivative or rate of change factor of the wetness measurements to determine whether a wetness event has occurred. The processor 310 compares this rate of change measurement to a predetermined rate of change level to make this determination. The faster the rate of change in the wetness measurement data, the more likely a wetness event has occurred. The rate of change factor can be used by itself or together with the sensitivity threshold level information to determine whether a wetness event has occurred. This allows the processor 310 to use two different types of data to decide whether or not a wetness event has occurred.

When the central computer system 300 receives resistance or wetness measurement data from the data collector 100 of a particular individual 5 indicative of a wetness event for that individual (e.g., five consecutive resistance measurements below the selected sensitivity level for that individual), the control computer 310 time stamps the wetness measurement data as a wetness event and associates this wetness event with the particular individual 5 wearing the subject transmitter 240. The processor 310 displays the name or otherwise identifies the individual 5 having the wetness event on the monitor 315, and the time the wetness event was time stamped, as indicated in the monitor display 315 or report shown in **Figure 15**. The monitor 315 or a report can also indicate the apartment or room number, or transmitter ID of the individual 5. The monitor 315 can also display other appropriate information, such as the name of the healthcare worker 7 assigned to the individual 5. The processor 310 may also sound an audible alarm at the nursing station.

The central computer system 300 then activates the base pager station 350 to send a page signal S4 to the pager 360 of an appropriate healthcare worker 7, as shown in **Figures 1a** and **1b**. The page signal S4 contains a message or appropriate information to identify the individual in

need of attention. For example, the page can indicate the individual's name, apartment or room number, transmitter ID, etc.

When the healthcare worker attends to the individual 5 and changes his or her wet garment 15 and sensor 30, the healthcare worker disconnects the wet or otherwise used sensor from the data collector 100. As discussed above, when the wet sensor 30 is removed, the data collector 100 determines that the wet sensor has been removed, but continues to gather and send infinite resistance measurement data to the central computer station 300 via signals S3, as indicated in **Figure 13**. When a new sensor 30 is properly attached to the data collector 100, the sensor detection circuit detects its presence. The data collector 100 continues using its wetness measurement circuit to determine the resistance of the new sensor 30, and transmits the signal S3 with resistance data every 140 seconds for about four to five minutes. After this four to five minute interval has elapsed, the data collector 100 stops transmitting resistance data at the faster 140 second rate. Once the new sensor strip 30 is properly attached to the data collector 100, the programming of the data collector 100 instructs it to transmit signals S3 at the slower 25 minute rate. The first slower rate signal S3 is sent about 25 minutes after the sensor is properly attached to the data collector 100, provided the wetness measurement data remains above the power conservation level of 5,000 ohms. The data collector 100 continues sending resistance data every 25 minutes until the processor 220 measures a resistance below the power conservation level (5,000 ohms) as discussed above.

The data collector 100 can be taken out of service by simply removing the wet or dry sensor 30 from the data collector and not replacing it with another sensor. If the sensor 30 is wet when it is removed and not replaced, the data collector will stop sending resistance data to the

central computer station 300 after four to five minutes. If the sensor 30 is dry when it is removed and not replaced, the data collector 100 will immediately stop sending resistance data.

The central computer system 300 considers a wet garment 15 changed when the resistance data received by the control computer 310 for a particular data collector 100 changes from a reading of below the power conservation level (5,000 ohms or less) to a reading of 50,000 ohms or greater. The computer 310 does not verify that the garment was changed until a signal S3 is received 25 minutes after the change event occurs. If no signal S3 is received at the 25 minute interval, the central computer 310 does not know whether a new garment was placed on the individual or whether the data collector 100 was simply taken out of service. When the central computer 310 determines that a garment change event has occurred, the computer time stamps this event, as shown in **Figure 15**. The control computer 310 stores at least the wetness measurement date and transmitter ID, and approximate time of each wetness event and each change event in its memory 312 or an associated memory.

The central computer system 300 generates reports via its printer 320 based on transmitter ID, individual name or assigned healthcare worker name. The report can take the form of a chart showing all the wetness measurement data obtained for a particular individual 5, as well as the time the data was received by the central computer station 300 as in **Figure 14**. The reports can also take the form of a chart identify the approximate times of all the wetness events change events for one or more individuals 5, to ensure that each person is consistently receiving prompt attention by the healthcare workers 7, as in **Figure 15**. The approximate duration of time between the wetness and change event for each person can also be noted or displayed.

The normal mode of operation for the data collector 100 has been described. However, it should be noted that the data collector 100 can be put into alternate modes during the set up, testing and servicing of the system 20. For example, an inferred transmission of encoded data can place the data collector 100 into a test mode where it sends resistance or wetness measurement data more frequently to aid in the manufacturing process and to demonstrate the system 20 and train the healthcare workers. The data collector 100 also has an internal counter that counts how many sensors 30 have been secured to the data collector. An inferred transmission of encoded data can instruct the data collector 100 to send this count to the central computer system 300. This count helps determine how much use the data collector 100 has had. An inferred transmission of encoded data can also be received by the data collector 100 to program a coded identification number into its wetness measuring circuit.

While the invention has been described with reference to a preferred embodiment, it will be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the broader aspects of the invention.

I claim:

1. A wetness monitoring apparatus for detecting wetness of an individual at a location of potential wetness, said wetness monitoring apparatus comprising:

a sensor formed by spaced conductors and an absorbent material, said conductors being spaced to produce an amount of resistance between said conductors, said absorbent material extending between said conductors and being adapted to absorb an amount of wetness, said amount of resistance between said conductors decreasing as said amount of wetness absorbed by said absorbent material increases, said sensor having an actual wetness value indicative of said amount of wetness absorbed by said absorbent material between said conductors, and said sensor being adapted for placement against the individual at the location of potential wetness;

a data collector having a data compiling processor, electric circuit, communication device and power source, said circuit including said spaced conductors of said sensor, said data compiling processor being programmed to use said circuit to obtain wetness measurement data corresponding to said actual wetness value of said sensor, and said data collector periodically generating and transmitting a data signal containing said wetness measurement data via said communication device; and,

a control station having a receiver, control processor and an associated memory containing a predetermined wetness value, said receiver receiving said periodic signals containing said wetness measurement data, said control processor being programmed to compare each of said wetness measurement data with said predetermined wetness value, said control processor being further programmed to determine that a wetness event has occurred when a predetermined number of said wetness measurement data exceed said predetermined wetness value.

2. The wetness monitoring apparatus of Claim 1, and wherein said control processor is programmed to store said wetness measurement data in its said associated memory.
3. The wetness monitoring apparatus of Claim 1, and wherein said control processor determines that a wetness event has occurred when said predetermined number of said wetness measurement data fall below said predetermined wetness value.
4. The wetness monitoring apparatus of Claim 1, and wherein said data compiling processor is programmed to use said circuit at spaced intervals of time to obtain said wetness measurement data, and wherein each of said wetness measurement data are taken at separate points of time, each of said wetness measurement data corresponding to said actual wetness value of said sensor at said point of time.
5. The wetness monitoring apparatus of Claim 4, and wherein said predetermined number of said wetness measurement data are a consecutive series of wetness measurement data.
6. The wetness monitoring apparatus of Claim 4, and wherein said data collector includes a data memory, and said data compiling processor is programmed to store each of said wetness measurement data in said data memory, and each of said data signals contains a plurality of said wetness measurement data in said data memory.

7. The wetness monitoring apparatus of Claim 6, and wherein said data compiling processor is programmed to retain only a given number of wetness measurement data in said data memory, said given number of wetness measurement data being said wetness measurement data obtained most recently by said data compiling processor, and wherein each of said data signals contains each of said given number of wetness measurement data in said data memory.

8. The wetness monitoring apparatus of Claim 1, and wherein said memory of said data collector contains a predetermined power conservation value, said data compiling processor comparing each of said wetness measurement data with said power conservation value, said data collector being programmed to generate and transmit said data signals at a first rate when said wetness measurement data is above said power conservation value, and at a second rate when one of said wetness measurement data falls below said power conservation value.

9. The wetness monitoring apparatus of Claim 1, and wherein said wetness monitoring apparatus is used for a number of individuals, and wherein said predetermined wetness value in said memory of said control processor is one of at least two separate sensitivity levels, and said control processor is programmed to allow one of the individuals to have a first sensitivity level and another individual to have a second sensitivity level.

10. The wetness monitoring apparatus of Claim 1, and wherein said wetness monitoring apparatus is for a number of individuals and a number of healthcare workers, each healthcare worker being assigned to at least one specific individual, and wherein each individual has an associated data collector, and each of said data collectors sends periodic signals having a unique

code that identifies the associated individual, and further includes a paging transmitter and a number of pagers, each healthcare worker having one of said pagers, and said control processor is programmed to use said paging transmitter to send a signal to said pager of the healthcare workers assigned to the specific individual having said wetness event.

11. The wetness monitoring apparatus of Claim 1, and wherein said absorbent material is formed by a garment worn by the individual.

12. The wetness monitoring apparatus of Claim 1, and wherein said data compiling processor applies a voltage potential across said circuit, and said wetness measurement data is resistance measurement data.

13. The wetness monitoring apparatus of Claim 1, and wherein said sensor is removable from said data collector, and said data collector is provided with contacts, each contact being adapted to electrically engage a corresponding conductor of said spaced conductors, and a sensor fastener for removably securing said sensor to said data collector with each of said contacts in electrical communication with its said corresponding conductor.

14. The wetness monitoring apparatus of Claim 13, and wherein said data collector has a second electric circuit for determining when said sensor is properly secured to said data collector and a second communication device, said data compiling processor being programmed to use said second circuit to detect an event when said contacts of said data collector are in electrical

engagement with said conductors of said sensor and to use said second communication device to communicate that said event has occurred.

15. The wetness monitoring apparatus of Claim 14, and wherein said data collector is provided with a garment fastener for removably securing said data collector to a garment worn by the individual.

16. The wetness monitoring apparatus of Claim 1, and wherein said resistance between said spaced conductors is substantially infinite when said absorbent material is in a dry condition, and said data compiling processor is programmed to designate a predetermined maximum wetness value for said actual wetness measurement value when in said dry condition.

17. The wetness monitoring apparatus of Claim 1, and wherein said sensor is a strip and said absorbent material is a pad.

18. The wetness monitoring apparatus of Claim 16, and wherein said sensor strip includes a backing layer, and said spaced conductors are sandwiched between and enclosed by said absorbent pad and said backing layer.

19. The wetness monitoring apparatus of Claim 1, and wherein said communication device is a radio frequency transmitter.

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20. A method of detecting wetness on an individual, said method of detecting wetness comprising the steps of:

providing a sensor formed by an absorbent material and spaced conductors, said conductors being spaced to produce an amount of resistance between said conductors, said absorbent material extending between said conductors and being adapted to absorb an amount of wetness, said amount of resistance between said conductors decreasing as said amount of wetness absorbed by said absorbent material increases, said sensor having an actual wetness value indicative of said amount of wetness absorbed by said absorbent material between said conductors, a data collector having a data compiling processor, electric circuit, communication device and power source, said circuit including said spaced conductors, and a control station having a receiver, control processor and associated memory containing a predetermined wetness value;

placing said sensor against the individual;

periodically obtaining wetness measurement data from said sensor at spaced intervals of time via said data collector, each of said wetness measurement data having a value indicative of said amount of wetness absorbed by said absorbent material at its corresponding interval of time;

periodically generating and transmitting said wetness measurement data from said data collector via said communication device to said control station via said receiver;

comparing each of said wetness measurement data with said predetermined wetness value;

determining that a wetness event has occurred when a predetermined number of said wetness measurement data exceed said predetermined wetness value; and,

communicating that said wetness event has occurred via said communication device of said control station.

21. The method of detecting wetness of Claim 20, and further including the step of storing said wetness measurement data in said associated computer of said control processor.

22. The method of detecting wetness of Claim 20, and wherein said associated memory of said control processor has a second predetermined wetness value, and further including a step of determining that a change event has occurred when said control processor receives wetness measurement data above a second predetermined value subsequent to a wetness event.

23. The method of detecting wetness of Claim 22, and wherein said control processor has an associated clock, and further including the steps of time stamping said wetness event, time stamping said change event, calculating a duration of time between said wetness and change events, and communicating said duration of time via said communication device of said control station.

24. The method of detecting wetness of Claim 20, and wherein said data collector includes a data memory, and further including the step of storing each of said wetness measurement data in said data memory, each of said data signals containing a given number of said wetness measurement data stored in said data memory.

25. The method of detecting wetness of Claim 24, and wherein said given number of wetness measurement data contained in one of said signals is fewer than said predetermined number of wetness measurement data needed to determine that a wetness event has occurred.
26. The method of detecting wetness of Claim 20, and wherein said data collector has a data memory containing a predetermined power conservation value, and further including the step of comparing each of said wetness measurement data with said power conservation value, said data collector generating and transmitting said data signals at a first rate when said wetness measurement data is above said power conservation value, and at a second rate when one of said wetness measurement data falls below said power conservation value.
27. The method of detecting wetness of Claim 20, and wherein said method of detecting wetness is for at least two different individuals, and further including a step of selecting said predetermined wetness value in said memory of said control processor from one of at least two sensitivity levels, a first sensitivity level being selected for one of the individuals and a second sensitivity level being selected for another of the individuals.
28. The method of detecting wetness of Claim 20, and further including the steps of removably connecting said sensor to said data collector to obtain wetness measurement data, disconnecting said sensor from said data collector after a wetness event has occurred, cleaning said sensor, and removably connecting said cleaned sensor to said data collector to obtain wetness measurement data.

29. The method of detecting wetness of Claim 20, and wherein said communication device of said control station includes a paging transmitter and a healthcare worker with a pager, and said step of communicating that said wetness event has occurred includes using said paging transmitter to send a page signal to said pager of the healthcare worker, said page signal containing a message indicating that the individual has had said wetness event.

30. The method of detecting wetness of Claim 20, and wherein said step of placing said sensor against the individual requires said sensor to be placed directly against the individual.

31. A data collection device for placement on an individual at a location of potential wetness, said data collection device comprising:

a sensor formed by spaced conductors and an absorbent material, said conductors being spaced to produce an amount of resistance between said conductors, said absorbent material extending between said spaced conductors and being adapted to absorb an amount of wetness, said amount of resistance between said conductors decreasing as said amount of wetness absorbed by said absorbent material increases, said sensor having an actual wetness value indicative of said amount of wetness absorbed by said absorbent material between said conductors, and said sensor being adapted for placement against the individual at the location of potential wetness; and,

a data collector having a data compiling processor, electric circuit, memory and power source, said circuit including said spaced conductors of said sensor, said data compiling processor being programmed to use said circuit at spaced intervals of time to obtain wetness

measurement data corresponding to said actual wetness value of said sensor, and said wetness measurement data being stored in said memory.

32. The data collection device of Claim 31, and wherein said data processor applies a voltage potential across said circuit, and said wetness measurement data is resistance measurement data.

33. The data collection device of Claim 31, and wherein said sensor is removable from said data collector, and said data collector is provided with contacts, each contact being adapted to electrically engage a corresponding conductor of said spaced conductors, and a sensor fastener for removably securing said sensor to said data collector with each of said contacts in electrical communication with its said corresponding conductor.

34. The data collection device of Claim 33, and wherein said data collector has a second electric circuit, said circuit being complete when at least one of said contacts is in electrical engagement with its said corresponding conductor, said data compiling processor being programmed to use said second circuit to determine when said sensor is properly secured to said data collector.

35. The data collection device of Claim 33, and wherein said data collector is provided with a garment fastener for removably securing said data collector to a garment worn by the individual.

36. The data collection device of Claim 31, and wherein said resistance between said spaced conductors is substantially infinite when said absorbent material is in a dry condition, and said

data compiling processor is programmed to designate a predetermined maximum wetness value for said actual wetness measurement value when in said dry condition.

37. The data collection device of Claim 31, and wherein said sensor is a strip and said absorbent material is a pad.

38. The data collection device of Claim 37, and wherein said sensor strip includes a backing layer, and said spaced conductors are sandwiched between and enclosed by said absorbent pad and said backing layer.

39. The data collection device of Claim 37, and wherein said conductors are substantially parallel to each other.

40. A method of tracking a number of times a semi-reusable wetness sensor is used, said method of tracking comprising the steps of:

providing a semi-reusable sensor and a data collector, said sensor having a predetermined number of unmarked indicia, and said data collector having an alignment mechanism, a securement mechanism and a marking mechanism;

selecting one of said unmarked indicia of said sensor;

aligning said selected unmarked indicia of said sensor with said alignment mechanism of said data collector;

securing said sensor to said data collector via said securing mechanism;

marking a mark on said sensor via said marking mechanism, said mark appearing adjacent said selected indicia;

using said sensor to determine when a wetness event occurs;

removing said sensor from said data collector;

cleaning said sensor;

repeating said steps of selecting, aligning, securing, marking, using, removing and cleaning said sensor until all but a single one of said predetermined number of indicia has an adjacent mark;

aligning said alignment mechanism of said data collector with said single one of said indicia, and repeating said steps of securing, marking, using and removing said sensor; and, removing said sensor from further use.

41. The method of tracking of Claim 40, and wherein said sensor is made of a deformable material, and said step of marking said sensor via said marking mechanism creates a lasting deformation in said sensor.

42. The method of tracking of Claim 41, and wherein said steps of securing said sensor and marking said sensor occur simultaneously.

43. The method of tracking of Claim 42, and wherein said indicia are holes extending through said sensor.

44. The method of tracking of Claim 43, and wherein said alignment mechanism is a pair of spaced posts, and each of said indicia are formed by a set of spaced holes, each set of said spaced holes being adapted to receive said spaced posts, and said step of aligning said sensor includes an alignment of one of said sets of spaced holes to receive said pair of posts.

45. The method of tracking of Claim 44, and wherein said sensor has longitudinal edges and a pair of spaced conductors extending along said length of said sensor, each conductor being a predetermined distance from one of said edges, and said data collector has a pair of spaced contacts, and wherein said step of aligning said sensor includes aligning each of said contacts to electrically engage one of said conductors.

46. The method of tracking of Claim 45, and wherein said contacts are adapted to pierce said sensor to electrically engage said conductors, and wherein said step of marking a mark on said sensor includes piecing said sensor strip.

47. The method of tracking of Claim 46, and wherein said sensor has a predetermined length defined by opposed ends, and said holes are located proximal one of said opposed ends.

48. The method of tracking of Claim 47, and wherein said securement mechanism is a sensor clamp.

49. The method of tracking of Claim 48, and wherein said alignment posts, sensor clamp and contacts combine to lock said sensor to said data collector.

50. A data collection device comprising:

a sensor strip having a layer of material, a top and bottom surface, and pair of conductive members, said conductive members being spaced a predetermined distance apart, and said sensor strip having a hole extending from said top surface through said bottom surface;

a data collector having a housing that holds an electric circuit, and said electric circuit having a pair of contacts that protrude through said housing, said contacts being spaced apart a distance substantially equal to said predetermined distance of said conductive members, said housing including an abutment adapted for alignment with said hole of said sensor;

a fastener adapted to secure said sensor to said data collector, said fastener being moveable between a release position and a secure position, said fastener being adapted to receive said sensor strip between said fastener and data collector when in said release position, and said fastener having a portion adapted to press said sensor strip against said contacts when in said secure position, said contacts piercing said sensor strip to electrically engage said conductive member when in said secure position; and,

a locking mechanism that locks said sensor strip to said data collector, said locking mechanism including said abutment, said abutment extending through said hole of said sensor strip when in said secure position.

51. The data collection device of Claim 50, and wherein said sensor strip includes a set of holes and said abutment is a set of posts, each of said holes in said set of holes being spaced a second predetermined distance apart, and said posts being spaced substantially said same second predetermined distance apart.

52. The data collection device of Claim 51, and wherein said portion of said fastener is a surface, and said surface includes post recesses for receiving said posts when said fastener is in said secure position.

53. The data collection device of Claim 52, and wherein said surface of said fastener includes contact recesses for receiving said contacts when said fastener is in said secure position.

54. The data collection device of Claim 53, and wherein said fastener is a U-shaped clamp having a middle portion and two ends, each of said ends snap fitting around said housing of said data collector, and said middle portion pressing said sensor strip against said contacts when in said secure position.

55. The data collection device of Claim 54, and wherein said posts and said contacts extend out from a surface of said housing and are substantially parallel, said posts extending further than said contacts, and said posts engaging said post recesses before said contacts engage said contact recesses when said fastener is being moved to said secure position, said posts guiding said contacts into alignment with said contact recesses.

56. The data collection device of Claim 55, and wherein said data collector has a U-shaped channel extending from said one side of said housing to an other side of said housing, and said contacts and posts extend from a bottom surface of said channel, and said U-shaped fastener is adapted to be received by said channel when in said secure position.

57. The data collection device of Claim 50, and wherein said posts are located between said contacts.

58. The data collection device of Claim 50, and wherein said sensor includes first and second layers of material, and said conductive members are positioned between and encased by said layers.

59. The data collection device of Claim 56, and wherein said first layer is an absorbent pad and second layer is a backing layer.

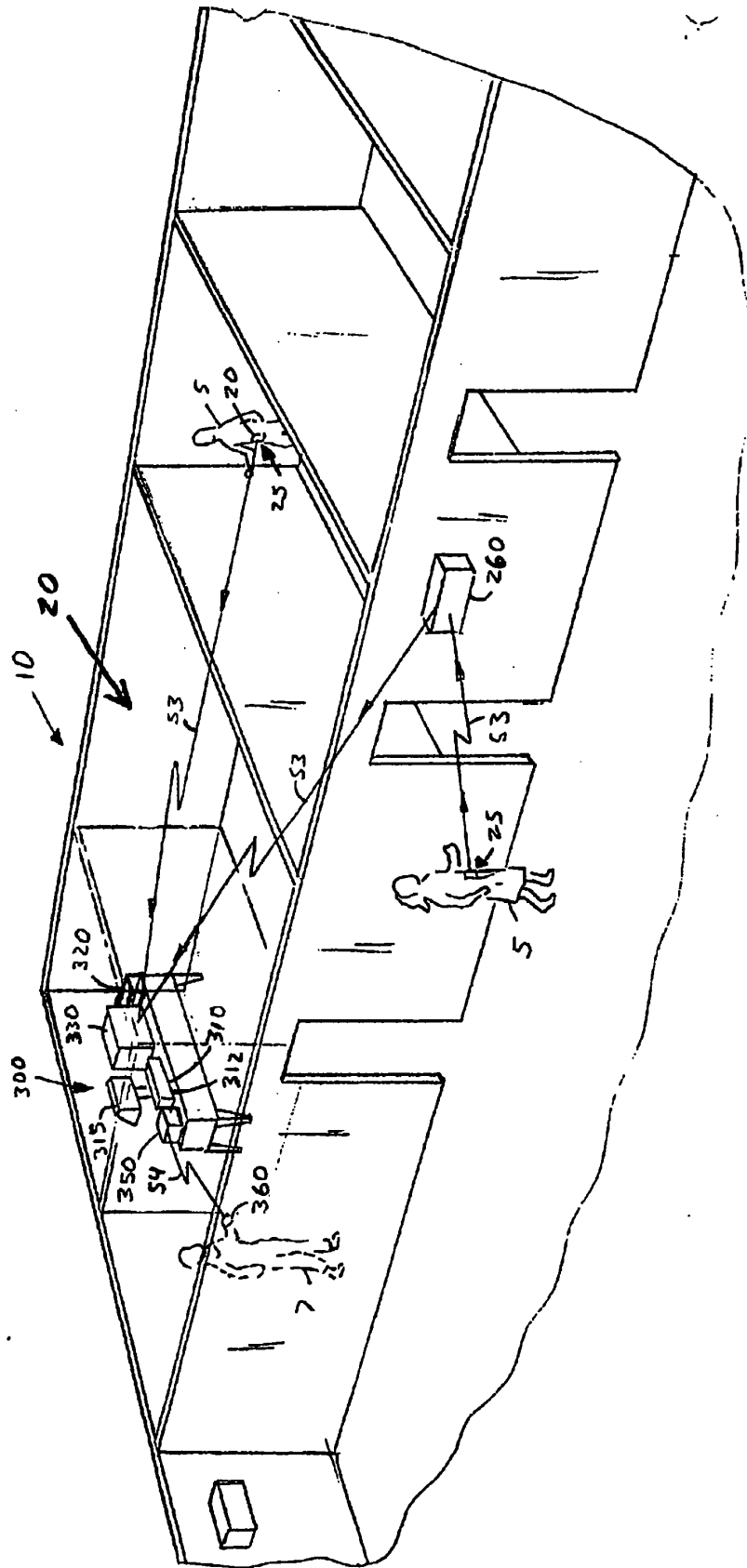
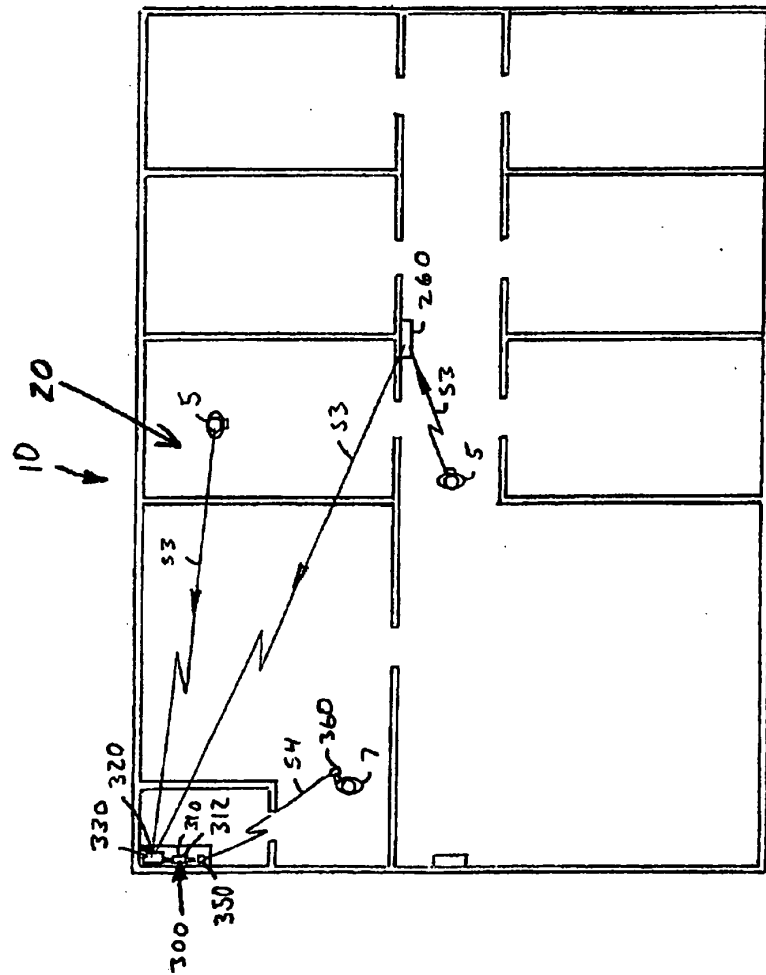
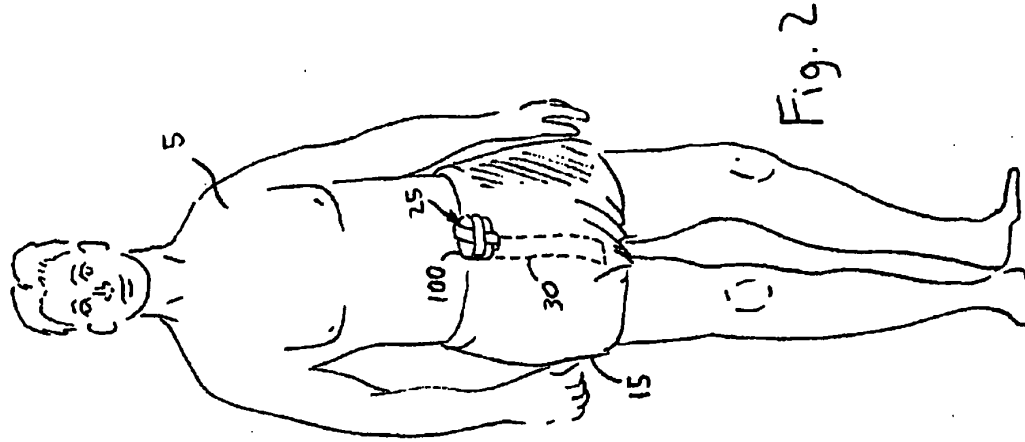


Fig. 1a



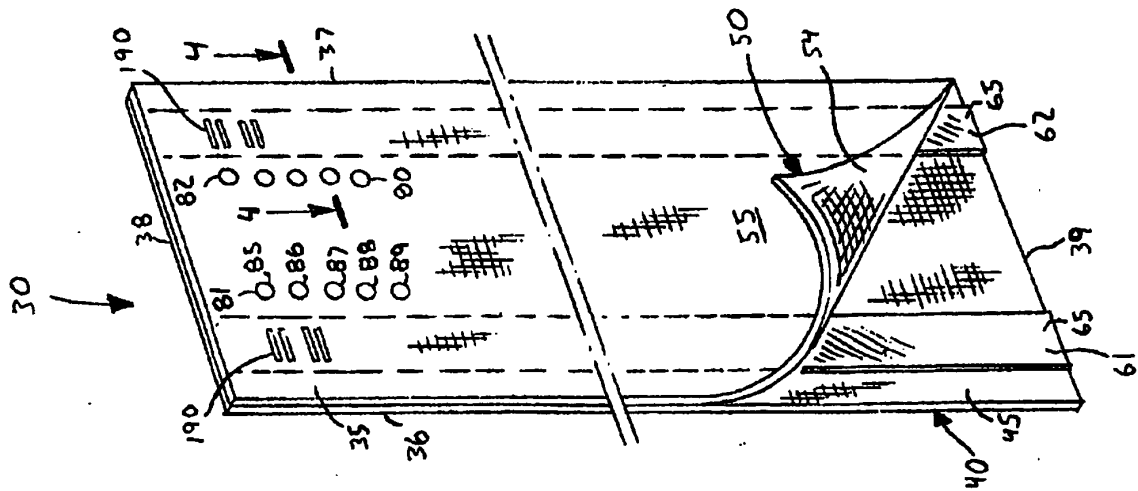


Fig. 3

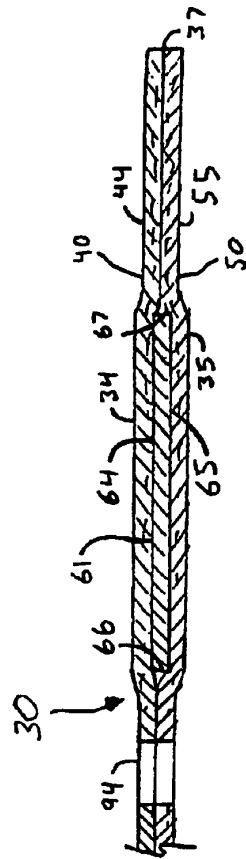


Fig. 4

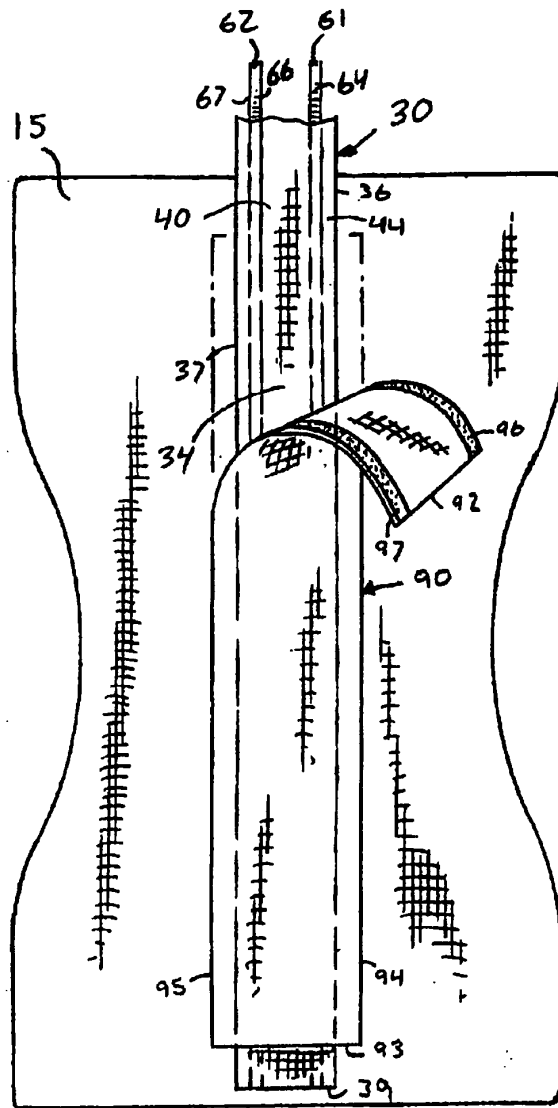


Fig. 5

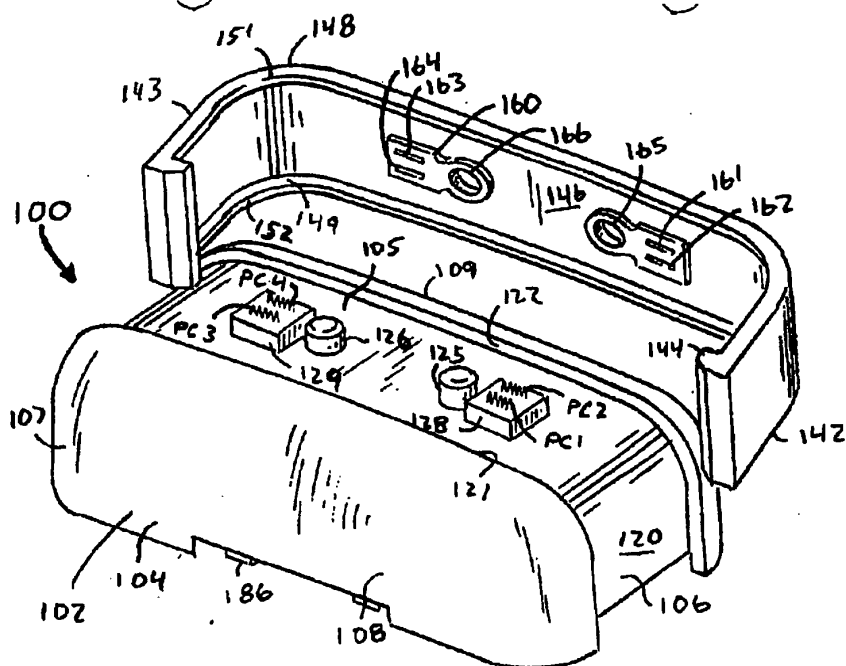


Fig. 6

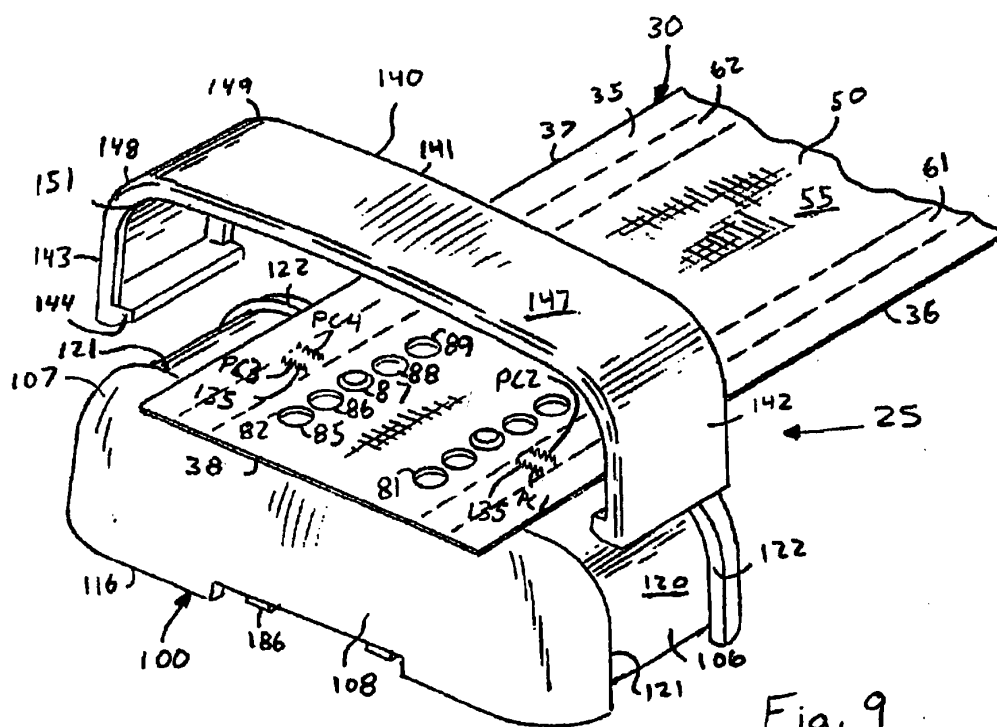


Fig. 9

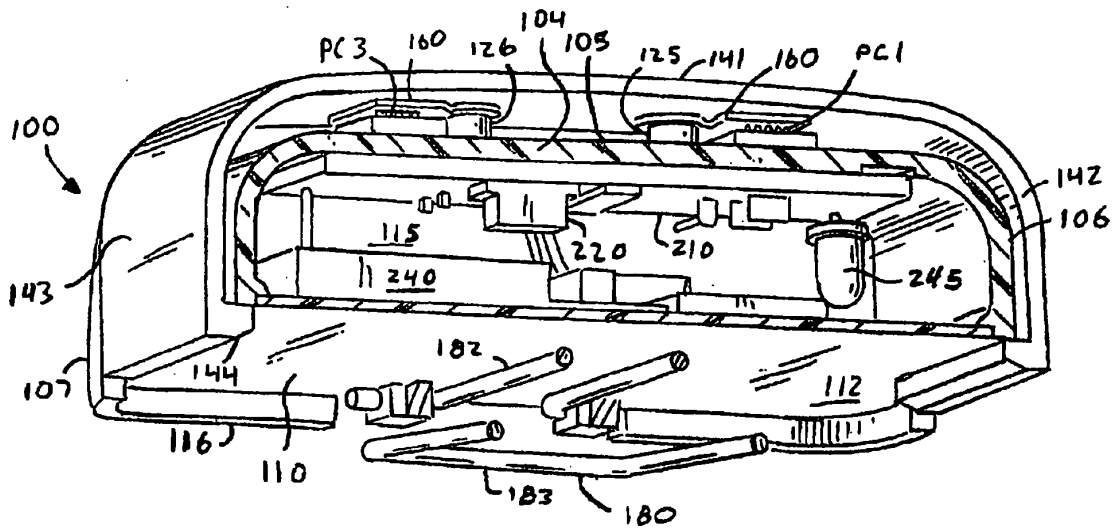


Fig. 7

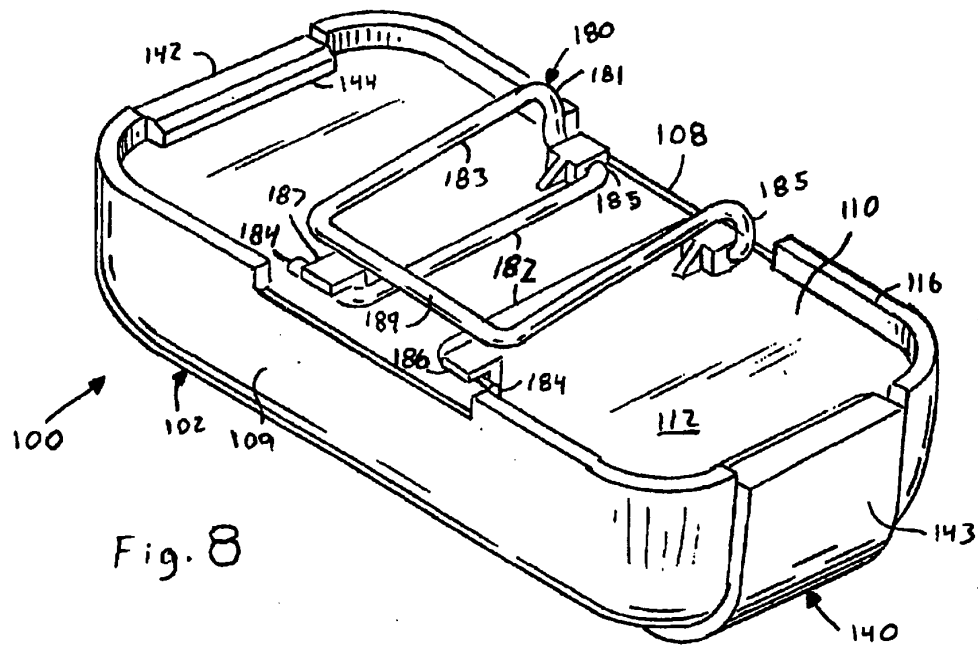


Fig. 8

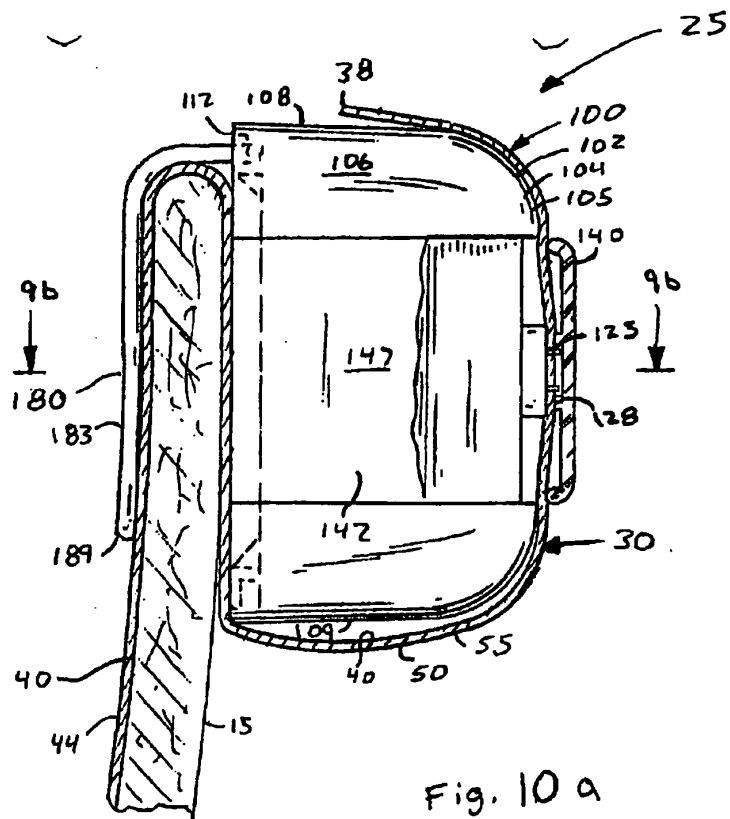


Fig. 10 a

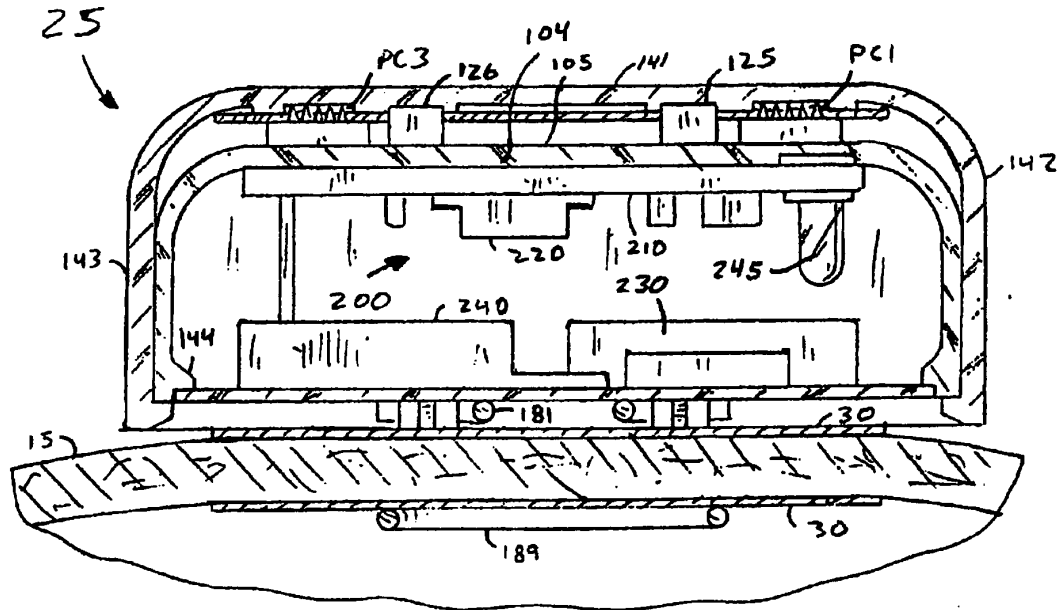


Fig. 10 b

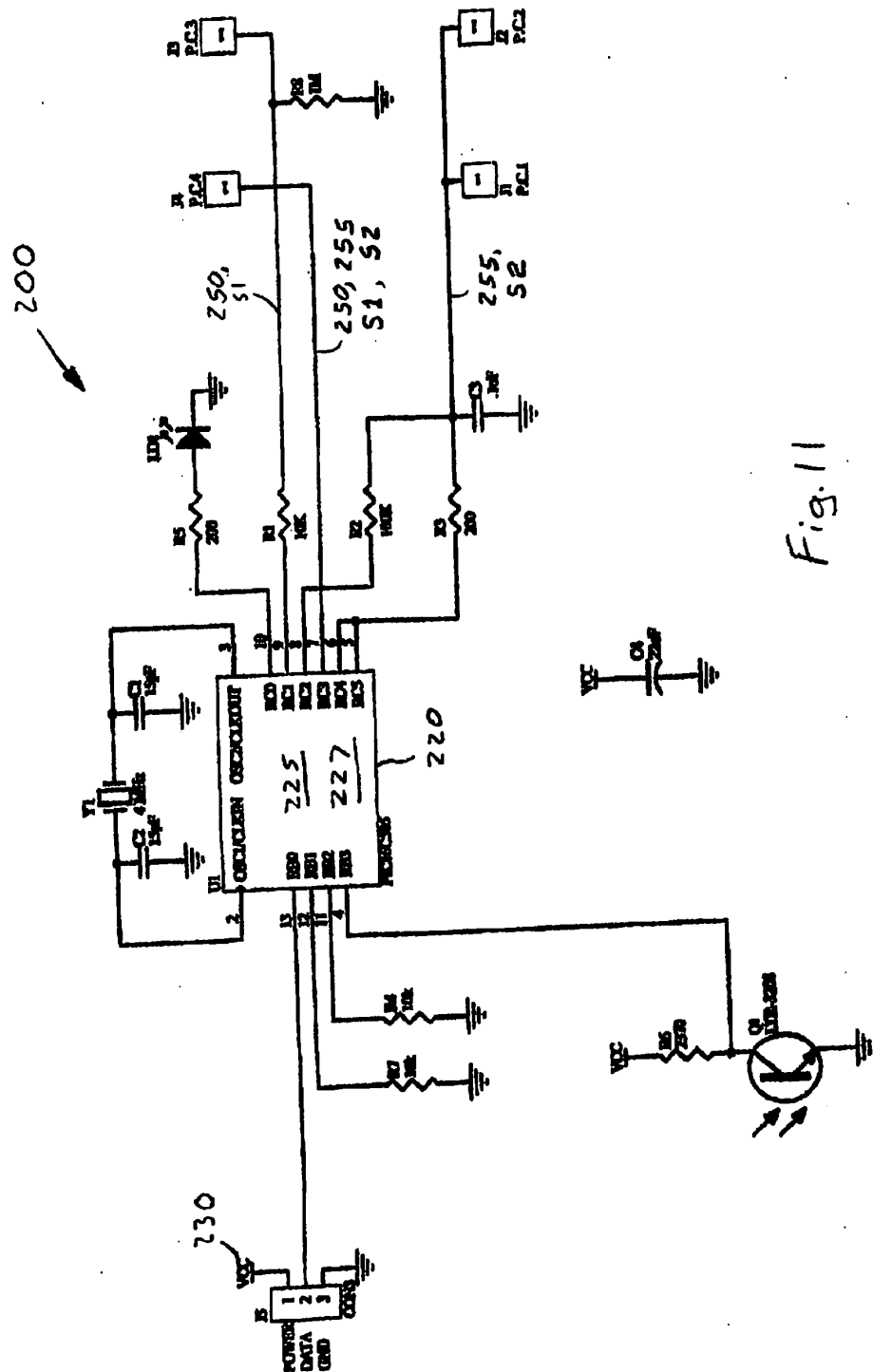
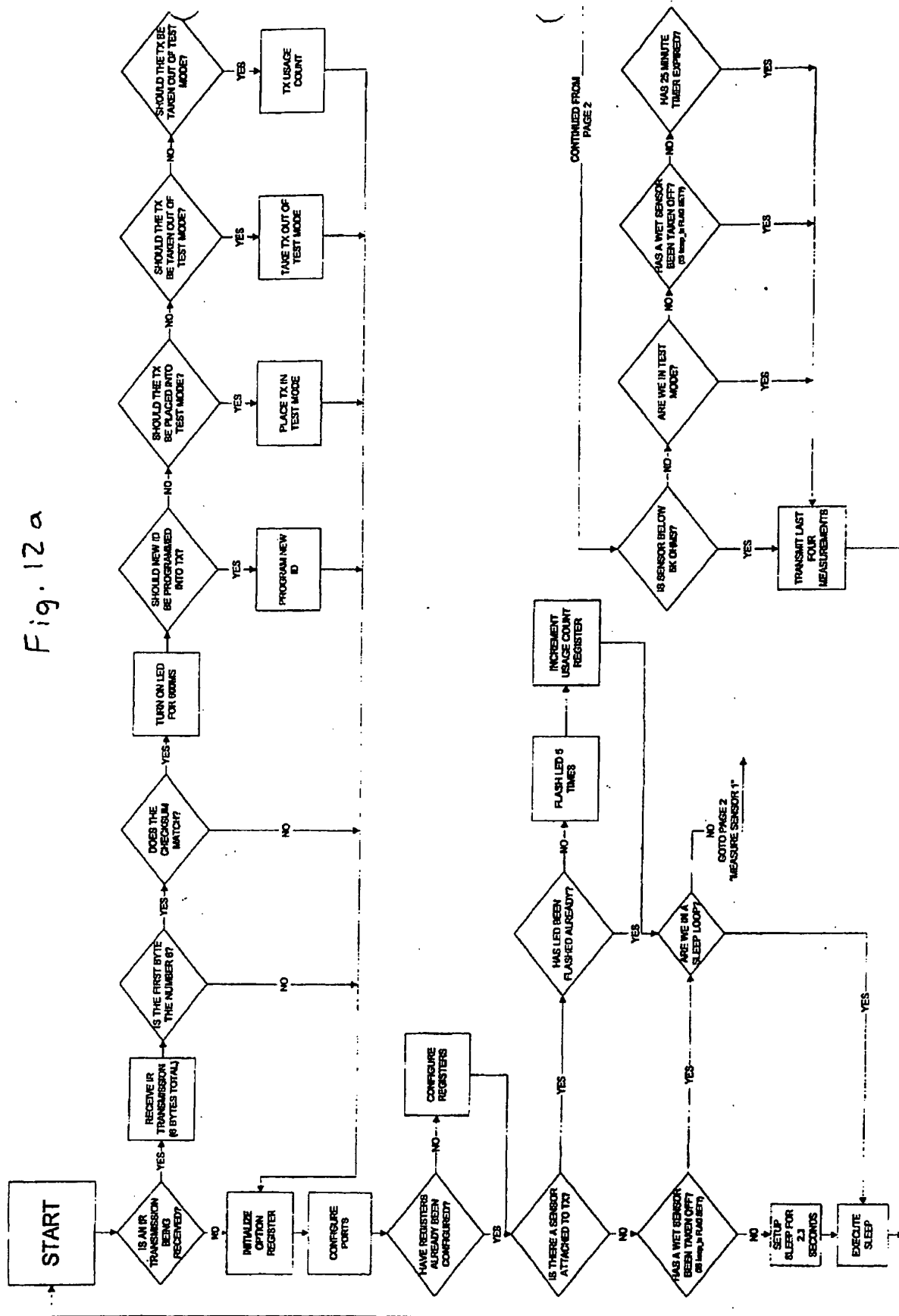
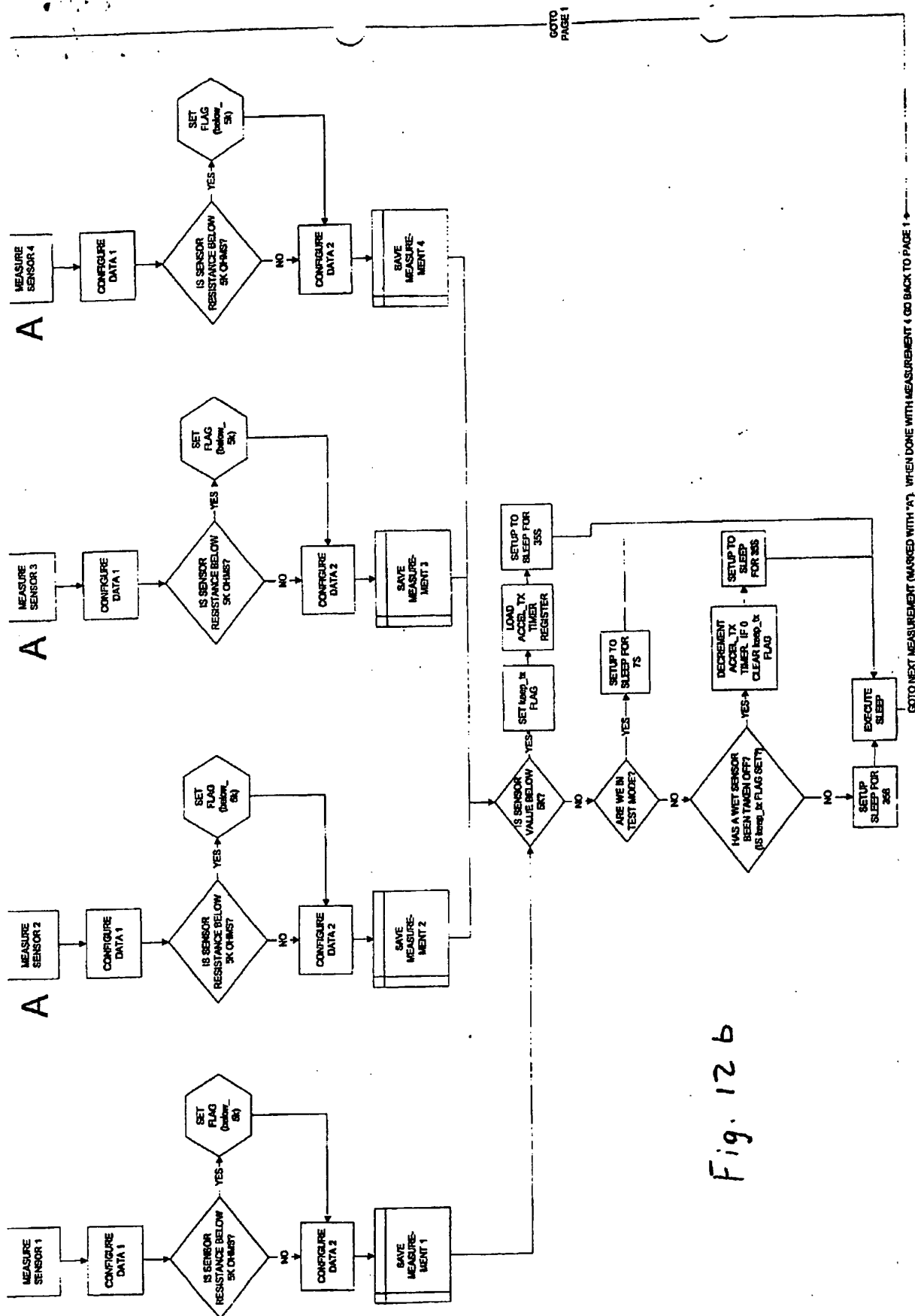
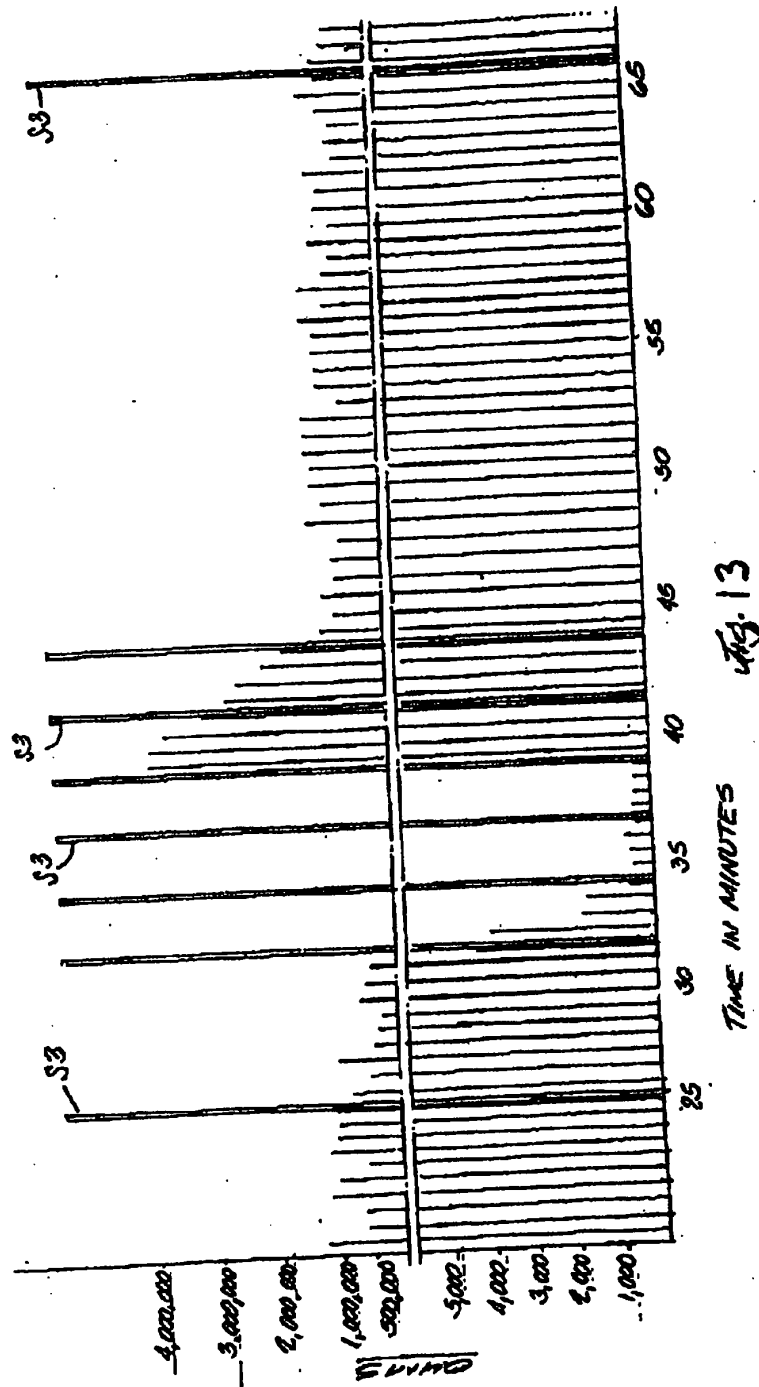


Fig. 12a







TIME	Measurement 1	Measurement 2	Measurement 3	Measurement 4	TAG
10:55:47 AM	4260000	4260000	4260000	4260000	51300
11:19:01 AM	632000	680000	634000	743000	51300
11:44:46 AM	1140000	1120000	116000	1050000	51300
12:10:04 PM	1670000	1370000	1640000	158000	51300
12:35:35 PM	77600	76100	77900	75000	51300
12:59:30 PM	28600	27900	27800	28800	51300
1:25:30 PM	21250	21230	21260	21200	51300
1:48:49 PM	21210	386	402	387	51300
1:50:19 PM	416	387	419	387	51300
1:52:44 PM	389	452	388	452	51300
1:55:13 PM	482	452	484	451	51300
1:57:41 PM	503	452	499	451	51300
2:00:08 PM	484	452	483	516	51300
2:02:34 PM	501	516	500	516	51300
2:05:00 PM	518	580	516	515	51300
2:07:27 PM	550	515	547	515	51300
2:10:06 PM	532	515	531	515	51300
2:12:22 PM	558	515	547	515	51300
2:15:02	555	515	547	579	51300
2:17:31	572	515	563	579	51300
2:20:05	4260000	4260000	4260000	4260000	51300
2:22:34 PM	4260000	4260000	4260000	4260000	51300
2:25:19 PM	4260000	4260000	4260000	4260000	51300
2:50:19 PM	632000	680000	634000	743000	51300

Fig. 14

Name	Date	Begin	End	Duration	Group
Mrs. Smith	10/12/2000	10:51 AM	11:01 AM	10 Minutes	Group A
Mrs. Johnson	10/12/2000	9:02 AM	9:20 AM	18 Minutes	Group A
Mrs. Heinze	10/13/2000	4:25 PM	4:45 PM	20 Minutes	Group A
Mr. Hill	10/13/2000	3:25 PM	3:55 PM	30 Minutes	Group A
Mrs. Berg	10/13/2000	8:10 AM	8:31 AM	21 Minutes	Group A
Mr. Smith	10/13/2000	11:07 AM	11:30 AM	23 Minutes	Group A

Fig. 15



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	05/02/2007	Frederick Bergman	P71951US0	6338

136	7590	10/21/2009
JACOBSON HOLMAN PLLC		
400 SEVENTH STREET N.W.		
SUITE 600		
WASHINGTON, DC 20004		

EXAMINER	
CHAPMAN, GINGER T	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
10/21/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/797,352		Applicant(s) BERGMAN ET AL.	
	Examiner Ginger T. Chapman		Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 02 May 2007.

2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-79 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application 6) <input type="checkbox"/> Other: _____.
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Application/Control Number: 11/797,352
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DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - Group I. Claims 1-23, drawn to a moisture monitoring system including an input, a processor and a user interface, classified in class 604, subclass 361.
 - Group II. Claims 24-42, drawn to a sensor, classified in class 128, subclass 920.
 - Group III. Claims 43-56, drawn to a method for monitoring moisture, classified in class 128, subclass 923.
 - Group IV. Claims 57-64, drawn to a diaper including a sleeve for insertion of a diagnostic strip, classified in class 600, subclass 300.
 - Group V. Claims 65-71, drawn to a diaper provided with a plurality of sensors, classified in class 600, subclass 309.
 - Group VI. Claims 72-74, drawn to a pad for transmitting signals representative of an aspect of fluids absorbed by said pad, classified in class 600, subclass 575.
 - Group VII. Claims 75-75, drawn to an incontinence management system including an article to be worn, sensing means and transmitting means, classified in class 600, subclass 388.
2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions Group I and Groups II, IV, V and VI are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for

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patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the system of Group I can be utilized with electrodes for fluid analysis. The subcombination has separate utility such as a catamenial pad for medical diagnostic evaluation of vaginal and reproductive secretions.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

4. Inventions Group I and Group VII are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have materially different mode of operation because the invention of Group I utilizes a diagnostic strip which can be an absorbent assay or reagent patch while the invention of Group VII utilizes sensors. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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5. Inventions Groups I & VII and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method can be practiced with a catamenial pad for medical diagnostic evaluation of vaginal and reproductive secretions.

6. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

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Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. A telephone call was made to Mr. John Holman on October 19, 2009 to request an oral election to the above restriction requirement, but did not result in an election being made.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


/Ginger T Chapman/
Examiner, Art Unit 3761
10/19/09

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761


✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant			<input type="checkbox"/> CPA			<input type="checkbox"/> T.D.			<input type="checkbox"/> R.1.47		
CLAIM		DATE									
Final	Original	10/19/2009									
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	2	+									
	3	+									
	4	+									
	5	+									
	6	+									
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	35	+									
	36	+									

<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant			<input type="checkbox"/> CPA			<input type="checkbox"/> T.D.			<input type="checkbox"/> R.1.47		
CLAIM		DATE									
Final	Original	10/19/2009									
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	38	+									
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<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant <input type="checkbox"/> CPA <input type="checkbox"/> T.D. <input type="checkbox"/> R.1.47										
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Final	Original	10/19/2009								
	73	÷								
	74	÷								
	75	÷								
	76	÷								
	77	÷								
	78	÷								
	79	÷								

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 6338
Frederick BERGMAN et al.	Attorney Docket No.: P71951US0
Serial No. 11/797,352	Group Art Unit: 3761
Filed: May 2, 2007	Examiner: Ginger T. CHAPMAN
For:	INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the restriction requirement set forth in the Official Action mailed October 21, 2009, please amend the claims and consider the following remarks regarding the above-captioned application.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 13 of this paper.

Appl. No. 11/797,352
Reply to Restriction Requirement of October 21, 2009

Attorney Docket No. P71951US0

Amendments to the Claims:

The listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Original) A moisture monitoring system for monitoring wetness in one or more absorbent articles, the system including:

an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article;

a processor for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article; and

user interface for communicating with a user of the system.

2. (Original) A moisture monitoring system according to claim 1 wherein the processor executes an algorithm to devise a mathematical model for characterising a wetness event in an absorbent article.

3. (Original) A moisture monitoring system according to claim 1 wherein the processor executes an algorithm to perform the analysis and wherein the algorithm applies uses the sensor signals and a pre-determined mathematical model to characterise a wetness event in an absorbent article by determining one or more of:

- (i) an estimated volume of exudate in a wetness event; and
- (ii) the nature of exudate in a wetness event.

4. (Original) A moisture monitoring system according to claim 1 wherein the processor uses sensor signals and/or variables derived from the sensor signals to derive one or more parameters suitable for use in a mathematical model for characterising a wetness event.

Appl. No. 11/797,352
Reply to Restriction Requirement of October 21, 2009

Attorney Docket No. P71951US0

5. (Original) A moisture monitoring system according to claim 3 wherein the algorithm applies variables derived from the one or more sensor signals to a pre-determined mathematical model to characterise a wetness event.

6. (Original) A moisture monitoring system according to claim 3 wherein the one or more sensor signals are indicative of one or more of:

- (i) conductivity of the exudate;
- (ii) temperature of the exudate;
- (iii) location of the exudate;
- (iv) pH of the exudate;
- (v) pressure within the absorbent article;
- (vi) odour within the absorbent article;
- (vii) presence of a gas in the absorbent article;
- (viii) presence of blood and/or a biological marker and/or a or chemical marker

in the exudate.

7. (Original) A moisture monitoring system according to claim 4 wherein variables derived from the sensor signals are selected from the group including:

- (i) area under a sensor signal curve;
- (ii) highest sensor signal value in a predetermined time period;
- (iii) maximum value of a leading edge of the sensor signal;
- (iv) rate of decay of sensor signal after a leading edge;
- (v) a volume estimated in a previous wetness event;
- (vi) time of onset of a wetness event;
- (vii) time of termination of a wetness event; and
- (viii) duration of a wetness event;
- (ix) time of day of a wetness event; and
- (x) time elapsed since last wetness event.

8. (Original) A moisture monitoring system according to claim 1 wherein the processor is configured to determine one or more of:

Appl. No. 11/797,352
Reply to Restriction Requirement of October 21, 2009

Attorney Docket No. P71951US0

- (a) a likelihood of an imminent wetness event;
- (b) an estimate of when a wetness event is likely to occur;
- (c) an estimate of a degree of fullness of an absorbent article; and
- (d) an estimate of when an absorbent article is likely to reach its absorbent capacity.

9. (Currently amended) A moisture monitoring system according to claim 1, wherein the user interface includes a wireless transmitter configured to transmit a signal to a user of the system to indicate that a predetermined volume of wetness has been detected in an absorbent article.

10. (Original) A moisture monitoring system according to claim 1 wherein the processor is configured to provide a toileting or voiding diary.

11. (Original) A moisture monitoring system according to claim 3 wherein the processor is configured to derive a toileting or voiding schedule for an individual, based on wetness events monitored using the monitoring system.

12. (Original) A moisture monitoring system according to claim 11 wherein the system is configured to predict, based on a derived toileting or voiding schedule, when an individual is likely to experience a wetness event which meets pre-defined criteria for manual checking.

13. (Original) A moisture monitoring system according to claim 1 wherein the system is further adapted to communicate automatically, an alert to a carer when one or more pre-defined criteria for manual checking are satisfied.

14. (Original) A moisture monitoring system according to claim 1 wherein the processor is configured to classify a possible form of incontinence suffered by a patient monitored by the system, the form of incontinence being selected from the group including urinary,

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Reply to Restriction Requirement of October 21, 2009

Attorney Docket No. P71951US0

fecal, dribble, stress, overflow, urge, mixed urinary (MUI), total and functional incontinence.

15. (Currently amended) A moisture monitoring system according to claim 1 wherein the processor is configured to perform one of recognizing and predicting the occurrence of ~~recognise and/or predict~~ lingering wetness in a region of an absorbent article.

16. (Original) A moisture monitoring system according to claim 1 wherein the processor is affixable to a sensor, an absorbent article or to a garment worn by a wearer of an absorbent article.

17. (Original) A moisture monitoring system according to claim 1 wherein the processor is incorporated into a central monitoring station adapted to receive sensor signals from a plurality of sensors associated with one or more absorbent articles.

18. (Original) A moisture monitoring system according claim 1 including a pre-processor associated with a sensor of an absorbent article.

19. (Currently amended) A moisture monitoring system according to claim 3, adapted to reconfigure the one or more mathematical models for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type, by:

for a training period using the particular individual, the different sensor type or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data; and

reconfiguring the mathematical model so that there is satisfactory correlation between ~~the wetness~~ estimates produced using the sensor signals and the reconfigured mathematical model, and wetness observations from the observation data obtained during the training period.

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Attorney Docket No. P71951US0

20. (Original) A moisture monitoring system according to claim 19 wherein reconfiguring a mathematical model involves determining one or more new parameters for the mathematical model.

21. (Original) A moisture monitoring system according to claim 19 wherein reconfiguring a mathematical model involves application of a linear regression algorithm.

22. (Original) A moisture monitoring system according to claim 19 wherein the observation data includes measurements indicating an amount of wetness in the absorbent article and time of measurement.

23. (Original) A moisture monitoring system according to claim 19 wherein the observation data includes one or more of:

demographic information; and
patient information.

24. (Currently amended) A moisture monitoring system according to claim 1 further including one or more sensors ~~sensor~~—for use with an absorbent article being monitored for wetness, the sensor including a plurality of sensor elements arranged in a pattern which provides an improved ability to detect wetness.

25. (Currently amended) A moisture monitoring system ~~sensor~~—according to claim 24 wherein the sensor elements are arranged in a pattern in which there are more sensor elements in regions having higher propensity for variable moisture or temperature.

26. (Currently amended) A moisture monitoring system ~~sensor~~—according to claim 24 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements extend beyond an edge thereof.

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27. (Currently amended) A moisture monitoring system sensor according to claim 26 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements extend beyond a front edge thereof.

28. (Currently amended) A moisture monitoring system sensor according to claim 24 further including, for each absorbent article being monitored, a signal receiver unit and a connector for connecting the sensor elements associated with an absorbent article to an associated -a signal receiver unit.

29. (Currently amended) A sensor-moisture monitoring system according to claim 24 further including, for each absorbent article being monitored, a cover layer over the sensor elements, the cover layer extending beyond an edge of the absorbent article and including means for enclosing a signal receiver unit attachable to one or more of the sensor elements.

30. (Currently amended) A moisture monitoring system sensor according to claim 24 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements are arranged for connection to a signal receiver unit outside the absorbent article.

31. (Currently amended) A moisture monitoring system sensor according to claims 28 wherein the signal receiver unit includes storage means for storing sensor signals collected over a period of time.

32. (Currently amended) A moisture monitoring system sensor according to claims 28 wherein the signal receiver unit includes means for receiving data relating to a patient's toileting activities.

33. (Currently amended) A moisture monitoring system sensor according to claim 24 wherein the pattern includes sensor elements positioned toward the sides of the absorbent article, near an opening for receiving a leg of the wearer.

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34. (Currently amended) A moisture monitoring system sensor—according to claim 24 wherein the pattern includes sensor elements located at two or more depths of the absorbent article.

35. (Currently amended) A moisture monitoring system sensor—according to claim 24 wherein the sensor includes a sensor substrate, the sensor substrate having one or more channels arranged between adjacent elements of the sensor.

36. (Currently amended) A moisture monitoring system sensor—according to claim 35 for use with an absorbent article having super absorbent material arranged in the article so as to draw fluid from the one or more channels in the sensor substrate.

37. (Currently amended) A moisture monitoring system sensor—according to claim 24 wherein the sensor is provided on a flexible substrate affixable, by adhesive or other means, to an absorbent article wearable by a user.

38. (Currently amended) A moisture monitoring system sensor—according to claim 24 wherein the sensor elements detect wetness at various identifiable locations with respect to the absorbent article, the locations selected from the group including:

- (a) toward the front of the absorbent article;
- (b) toward the rear of the absorbent article;
- (c) toward a side of the absorbent article; and
- (d) substantially centrally of the absorbent article.

39. (Currently amended) A moisture monitoring system sensor—according to claim 24 wherein the pattern of sensor elements facilitates improved detection of moisture from a user in a range of positions including standing, sitting, lying prone, lying supine and lying on the side.

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Attorney Docket No. P71951US0

40. (Currently amended) A moisture monitoring system sensor according to claim 24 wherein the sensor elements are arranged to detect spread of moisture from a wetness event in two or more directions.

41. (Currently amended) A moisture monitoring system sensor according to claim 24 wherein the sensor pattern includes one or more of:

- elongate sensor elements;
- sensor elements arranged in a grid; and
- an array of sensor element dots.

42. (Currently amended) A moisture monitoring system sensor according to claim 24 wherein the sensor includes sensor elements for detecting one or more of electrical conductivity, temperature, pressure, pH, odour, gas and presence of a biological or chemical marker in exudate and location of exudate.

43 – 56 (Cancelled)

57. (Currently amended) A diaper for a person to wear, for use with the moisture monitoring system of claim 1 ~~in an incontinence management system or a system for the management of exudates from the body of a person, characterised in that~~ wherein said diaper includes a sleeve for the insertion of a diagnostic strip.

58. (Original) A diaper according to claim 57 characterised in that said sleeve is located on said diaper close to, in use, the pubic area of a wearer.

59. (Original) A diaper according to claim 57, characterised in that said diaper has means designed to direct fluids excreted by said person, to said sleeve.

60. (Original) A diaper according to claim 57, characterised in that said sleeve is provided with a V-shaped notch to facilitate the insertion of a diagnostic strip.

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61. (Original) A diaper according to claim 57, characterised in that said sleeve is attachable to said diaper by adhesive material.

62. (Original) A diaper according to claim 59, characterised in that said means designed to direct fluids excreted by said person, to said sleeve, is constituted by pores and/or channels.

63. (Original) A diaper according to claim 62, characterised in that said pores and/or channels are located around the periphery of said sleeve.

64. (Original) A diaper according to claim 57, characterised in that sleeve is adapted to retain a predetermined amount of exudate to facilitate contact of said exudate with said strip.

65. (Currently amended) A diaper for a person to wear, for use ~~in~~ with the moisture monitoring system of claim 1 wherein an incontinence management system or a system for the management of exudates from the body of a person, characterised in that said diaper is provided with a plurality of sensors at different locations in said diaper.

66. (Original) A diaper according to claim 65, characterised in that said sensors are wetness sensors.

67. (Original) A diaper according to claim 66, characterised in that said sensors are adapted to permit the estimation of the volume of exudate flowing from the patient in real time.

68. (Original) A diaper according to claim 67, characterised in that the volume of exudate passed by the person wearing said diaper, preferably in a unit of time, is established using a mathematical model computed by using such factors as the distance between said sensors, the rate of transfer of moisture between said sensors, and the

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absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres.

69. (Original) A diaper according to claim 65, characterised in that data from said sensors is transmitted using radio technology, and in that said data is processed using software running the aforementioned mathematical model.

70. (Original) A diaper according to claim 65, characterised in that each of said sensors is constituted by conductive inks.

71. (Original) A diaper according to claim 65, characterised in that the spacing of said sensors is at different thicknesses in material forming at least a part of said diaper.

72. (Currently amended) A pad for use with a diaper, and the moisture monitoring system of claim 1, said pad being associated with transmitting means, for transmitting signals representative of an aspect of fluids absorbed by said pad, to a remote location.

73. (Original) A diaper according to claim 72, characterised in that said pad includes a chamber for collection of said fluids.

74. (Original) A diaper according to claim 73, characterised in that said chamber is removable.

75 – 79 (Cancelled)

80. (New) A moisture monitoring system according to claim 1 configurable to adapt a mathematical model to characterise a wetness event in an absorbent article being monitored using one or more of a new sensor type, new sensor element and a new type of absorbent article not previously used with the moisture monitoring system.

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81. (New) A moisture monitoring system according to claim 1 wherein the processor is configured to receive automatically data pertaining to known features of an absorbent article selected from a group including: volume capacity, type, brand and location of sensors embedded therein.

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Reply to Restriction Requirement of October 21, 2009

Attorney Docket No. P71951US0

REMARKS

Restriction Requirement

The Examiner has required the Applicant to elect one of the following inventions for further examination:

- Group I: Claims 1 – 23, drawn to a moisture monitoring system;
- Group II: Claims 24 – 42, drawn to a sensor;
- Group III: Claims 43 – 56, drawn to a method for monitoring moisture;
- Group IV: Claims 57 – 64, drawn to a diaper with a sleeve;
- Group V: Claims 65 – 71, drawn to a diaper with sensors;
- Group VI: Claims 72 – 74, drawn to a pad;
- Group VII: Claims 75 – 79, drawn to incontinence management system.

Applicant elects the invention of Group I, drawn to a moisture monitoring system, for further examination **without traverse**. The claims readable on the elected invention are Claims 1 – 42, 57 – 74 and 80 – 81 as amended.

Claims 43 – 56 and 75 – 79 have been cancelled without prejudice or disclaimer. Claims 9, 15, 19, 24 – 42, 57, 65 and 72 have been amended to correct informalities or further specify the present invention. New Claims 80 – 81 have been added to further specify the present invention. The basis for the new claims can be found on page 13, lines 26 – 28, 30 – 35 and page 16, lines 1 – 5 of the specification. It is respectfully submitted that the amendment is sufficiently supported by the specification and no new matter has been introduced by the amendment.

It is respectfully submitted that Applicant preserves the right to file divisional application(s) directed to the non-elected invention.

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Reply to Restriction Requirement of October 21, 2009

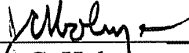
Attorney Docket No. P71951US0

Therefore, an action on the merits of all of the claims and a Notice of Allowance thereof are respectfully requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Date: January 21, 2010
(202) 638-6666
400 Seventh Street, N.W.
Washington, D.C. 20004
Atty. Dkt. No.: P71951US0

By 
John C. Holman
Registration No. 22,769

Electronic Patent Application Fee Transmittal				
Application Number:	11797352			
Filing Date:	02-May-2007			
Title of Invention:	Incontinence management system and diaper			
First Named Inventor/Applicant Name:	Frederick Bergman			
Filer:	John Clarke Holman/Laura Bell			
Attorney Docket Number:	P71951US0			
Filed as Small Entity				
Utility under 35 USC 111(a) Filing Fees				
Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Extension - 2 months with \$0 paid	2252	1	245	245

Description	Fee Code	Quantity	Amount	Sub-Total in USD(\$)
Miscellaneous:				
Total in USD (\$)				245

Electronic Acknowledgement Receipt	
EFS ID:	6853816
Application Number:	11797352
International Application Number:	
Confirmation Number:	6338
Title of Invention:	Incontinence management system and diaper
First Named Inventor/Applicant Name:	Frederick Bergman
Customer Number:	00136
Filer:	John Clarke Holman/Laura Bell
Filer Authorized By:	John Clarke Holman
Attorney Docket Number:	P71951US0
Receipt Date:	21-JAN-2010
Filing Date:	02-MAY-2007
Time Stamp:	14:15:42
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	Credit Card
Payment was successfully received in RAM	\$245
RAM confirmation Number	580
Deposit Account	
Authorized User	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
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1		p71951lamend.pdf	1293805 7ccbee03ac29a086366ef86c26d5c11479559462	yes	16
Multipart Description/PDF files in .zip description					
	Document Description	Start	End		
	Miscellaneous Incoming Letter	1	1		
	Extension of Time	2	2		
	Amendment/Req. Reconsideration-After Non-Final Reject	3	3		
	Claims	4	14		
	Applicant Arguments/Remarks Made in an Amendment	15	16		
Warnings:					
Information:					
2	Fee Worksheet (PTO-875)	fee-info.pdf	29822 f999ba86af4657bd3cbf4fe70d9a568f705c2b4d	no	2
Warnings:					
Information:					
Total Files Size (in bytes):			1323627		
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>					

PATENT**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Frederick BERGMAN et al. Attorney Docket: P71951US0

Serial No.: 11/797,352 Group Art Unit: 3761

Filing Date: May 2, 2007 Examiner: Ginger T. CHAPMAN

For: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

TRANSMITTAL

Mail Stop Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Transmitted herewith is a Response to the restriction requirement in the above captioned application.

XX Small Entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.

The fee has been calculated as shown below:

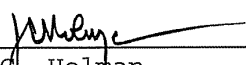
Claims Remaining After Amendment	Highest Number Previously Paid For	Present Extra	Small Entity Rate Addit. (or) Fee	Other Than A Small Entity Rate Addit. Fee
Total	62	- 79 = 0	x26 = \$	x 52 = \$
Indep.	1	- 7 = 0	x110 = \$	x 220 = \$
Two-month extension of time			\$245.00	\$
Total Additional Fee			\$245.00	\$

XX Credit Card Payment Form in the amount of \$245.00 is attached for extension fee.

XX If a Petition for Extension of Time is necessary and the Petition and/or the check is not enclosed, this will act as the Petition and applicant herewith petitions the Commissioner to extend the time for response and charge any fees necessary under 37 CFR 1.17 (a)(1)-(5) to Deposit Account No. 06-1358. The Commissioner is also authorized to charge payment of any other additional fees associated with this communication or credit any overpayment to Deposit Account No. 06-1358. A duplicate copy of this sheet is attached.

JACOBSON HOLMAN, PLLC

Dated: January 21, 2010
 400 Seventh Street, N. W.
 Washington, D.C. 20004-2201
 P71951US0
 JCH/JC

By: 
 John C. Holman
 Reg. No. 22,769

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 6338
Frederick BERGMAN et al.	Attorney Docket No.: P71951US0
Serial No. 11/797,352	Group Art Unit: 3761
Filed: May 2, 2007	Examiner: Ginger T. CHAPMAN
For:	INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

PETITION FOR EXTENSION OF TIME


Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Petition for Extension of Time for a two-month period. This Petition for Extension of Time is being concurrently filed with a Response. A Credit Card Payment Form (PTO-2038) authorizing payment in the amount of \$245.00 is enclosed. If the Examiner should find a discrepancy in the fees owed, please debit or credit Deposit Account No. 06-1358.

Respectfully submitted,

JACOBSON HOLMAN, PLLC

By 
John C. Holman
Reg. No. 22,769

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666
Date: January 21, 2010

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/797,352		Filing Date 05/02/2007		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)		SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY			
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =		OR	X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =			X \$ =				
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY OR		OTHER THAN SMALL ENTITY	
AMENDMENT	01/21/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 62	Minus	** 79 = 0	X \$26 =	0	OR	X \$ =		
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 7 = 0	X \$110 =	0	OR	X \$ =		
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)		(Column 3)		SMALL ENTITY OR		OTHER THAN SMALL ENTITY	
AMENDMENT		CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	*	Minus	** =	X \$ =		OR	X \$ =		
	Independent (37 CFR 1.16(h))	*	Minus	*** =	X \$ =		OR	X \$ =		
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

Legal Instrument Examiner:
/ROZENIA HARMON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

JA0772

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/797,352		Filing Date 05/02/2007		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =		OR	X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =			X \$ =				
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	01/21/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
	Total (37 CFR 1.16(i))	* 62	Minus	** 79	= 0	X \$26 =	0	OR	X \$ =	
	Independent (37 CFR 1.16(h))	* 1	Minus	*** 7	= 0	X \$110 =	0	OR	X \$ =	
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
TOTAL ADD'L FEE						0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)		
	Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	OR	X \$ =		
	Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	OR	X \$ =		
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
TOTAL ADD'L FEE							OR	TOTAL ADD'L FEE		
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3. ** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20". *** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3". The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

Legal Instrument Examiner:
/ROZENIA HARMON/

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

JA0773



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	05/02/2007	Frederick Bergman	P71951US0	6338

136	7590	04/28/2010
JACOBSON HOLMAN PLLC		
400 SEVENTH STREET N.W.		
SUITE 600		
WASHINGTON, DC 20004		

EXAMINER	
CHAPMAN, GINGER T	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
04/28/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/797,352		Applicant(s) BERGMAN ET AL.	
	Examiner Ginger T. Chapman		Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 21 January 2010.

2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-42, 57-74, 80 and 81 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claim(s) 1-42, 57-74 and 80-81 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application 6) <input type="checkbox"/> Other: _____.
---	--

Application/Control Number: 11/797,352
Art Unit: 3761

Page 2

DETAILED ACTION

Status of the Claims

1. Claims 43-56 and 75-79 are cancelled, claims 80-81 are added, claims 9, 15, 19, 24-42, 57, 65 and 72 are amended, claims 1-42, 57-74 and 80-81 are pending in the application; claims 24-42 and 57-74 are withdrawn from consideration as being drawn to a nonelected invention.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 1-23, in the reply filed on 01/21/2010 is acknowledged.
3. Claims 43-56 and 75-79 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/21/2010.
4. This application contains claims directed to the following patentably distinct species:
 1. **Species 1**: processor executes an algorithm to devise a mathematical model (not show in the figures) as per **claims 1 and 2**;
 2. **Species 2**: processor executes and algorithm to perform analysis using sensor signals and a pre-determined mathematical model (not shown in the figures) as per **claims 1, 3, 5-6, 11-12, 19-23 and 81**;
 3. **Species 3**: processor uses sensor signals and variables derived from sensor signals to derive parameters (not shown in the figures) as per **claims 1, 4 and 7**;
 4. **Species 4**: processor configured to determine likelihoods, estimates and schedules, as per **claims 1, 8, 10, 11 and 14-18**;

Application/Control Number: 11/797,352
Art Unit: 3761

Page 3

5. **Species 5:** system configured to transmit, predict, communicate wetness (not shown in the figures) as per **claims 1, 9, 12-13 and 80;**

5. The species are independent or distinct because claims to the different species recite the mutually exclusive characteristics of such species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as

Application/Control Number: 11/797,352
Art Unit: 3761

Page 4

an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

6. A telephone call was made to Mr. Jiwen Chen for Mr. J. Holman on 03/01/2010 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of

Application/Control Number: 11/797,352
Art Unit: 3761

Page 5

election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention or species.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 11/797,352
Art Unit: 3761


Page 6

/Ginger T Chapman/
Examiner, Art Unit 3761
04/14/10
/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761

<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761


✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

<input type="checkbox"/> Claims renumbered in the same order as presented by applicant				<input type="checkbox"/> CPA				<input type="checkbox"/> T.D.				<input type="checkbox"/> R.1.47			
CLAIM		DATE													
Final	Original	10/19/2009	04/14/2010												
	1		+												
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	3		+												
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<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
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CLAIM		DATE													
Final	Original	10/19/2009	04/14/2010												
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<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761


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CLAIM		DATE							
Final	Original	10/19/2009	04/14/2010						
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<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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CLAIM		DATE							
Final	Original	10/19/2009	04/14/2010						
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<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Frederick BERGMAN et al.

Confirmation No.: 6338

Serial No. 11/797,352

Group Art Unit: 3761

Filed: May 2, 2007

Examiner: Ginger T. Chapman

For: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

RESPONSE TO ELECTION/RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Election of Species Requirement mailed April 28, 2010, kindly set forth the following remarks in the above-captioned application.

U.S. Patent Application No. 11/797,352

Page 2

REMARKS

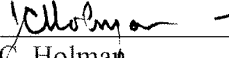
This is submitted as a full and complete response to the outstanding Election of Species Requirement. The Examiner had made an Election Requirement which was responded to and the elected claims are now subject to a Species Election. The Examiner has set forth five Species on pages 2 and 3 of the Official Letter mailed April 28, 2010. The applicant herewith elects to continue prosecution on Species 1, which is set forth in claims 1 and 2. This election is made without traverse.

It is understood that claims 1 is generic and if claim 1 is found allowable or if claim 1 amended with some or all of the limitations of claim 2 is found allowable, then all of the non-elected claims that directly or indirectly depend from these allowed claims should also be found allowable.

Early and favorable action on claims 1 and 2 is courteously awaited.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: 
John C. Holman
Reg. No. 22769

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666

Atty. Docket: P71951US0
Date: May 21, 2010

Electronic Acknowledgement Receipt	
EFS ID:	7665808
Application Number:	11797352
International Application Number:	
Confirmation Number:	6338
Title of Invention:	Incontinence management system and diaper
First Named Inventor/Applicant Name:	Frederick Bergman
Customer Number:	00136
Filer:	John Clarke Holman/K. Jeffrey de Hart
Filer Authorized By:	John Clarke Holman
Attorney Docket Number:	P71951US0
Receipt Date:	21-MAY-2010
Filing Date:	02-MAY-2007
Time Stamp:	18:26:06
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no
------------------------	----

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Response to Election / Restriction Filed	P71951US0_response.pdf	49330 a90737064243df70be8b4f57a109540a661682c2	no	2

Warnings:**Information:**

JA0788

Total Files Size (in bytes):	49330
<p>This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.</p> <p><u>New Applications Under 35 U.S.C. 111</u> If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.</p> <p><u>National Stage of an International Application under 35 U.S.C. 371</u> If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.</p> <p><u>New International Application Filed with the USPTO as a Receiving Office</u> If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.</p>	



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UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	05/02/2007	Frederick Bergman	P71951US0	6338

136	7590	06/08/2010
JACOBSON HOLMAN PLLC		
400 SEVENTH STREET N.W.		
SUITE 600		
WASHINGTON, DC 20004		

EXAMINER	
CHAPMAN, GINGER T	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
06/08/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 11/797,352		Applicant(s) BERGMAN ET AL.	
	Examiner Ginger T. Chapman		Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 21 May 2010.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-74,80 and 81 is/are pending in the application.

4a) Of the above claim(s) 3-74,80 and 81 is/are withdrawn from consideration.

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6) ☒ Claim(s) 1 and 2 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>09/30/2008</u> .	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____. 5) <input type="checkbox"/> Notice of Informal Patent Application 6) <input checked="" type="checkbox"/> Other: <u>WO</u> .
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Application/Control Number: 11/797,352
Art Unit: 3761

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DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in Application No. 11/797,352, filed on 07/25/2007.

Election/Restrictions

1. Applicant's election without traverse of Species 1, claims 1-2, in the reply filed on 05/21/2010 is acknowledged.
2. Claims 3-74 and 80-81 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/21/2010.

Status of the Claims

3. Claims 75-79 are cancelled, claims 1-74 and 80-81 are pending in the application, claims 3-74 and 80-1 are withdrawn from consideration as being drawn to a nonelected invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bergman (WO 96/14813).
6. With respect to claim 1, Bergman discloses:

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A moisture monitoring system for monitoring wetness in one or more absorbent articles (page 1, lines 3-4 and page 3, lines 19-20), the system including:

an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article (page 1, lines 33-34);

a processor for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article (page 2, line 9; page 1, lines 34-39);
and

user interface for communicating with a user of the system (page 4, lines 30-38; page 6, line 38 to page 7, lines 1-3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergman in view of Panopoulos (US 2004/0220538).

10. With respect to claim 2, Bergman discloses the claimed invention except for expressly disclosing the wherein the processor executes an algorithm to devise a mathematical model for characterising a wetness event in an absorbent article. Algorithms are known for calculation and data processing functions. The instant Specification at paragraphs [0017, 0018, 0025, 0035, 0036, 0061, 0062, 0064, 0065] that the instant algorithm characterizes wetness events such as nature of exudates (either urinary or fecal), volume of discharge, and applies the sensor signals to predict when a patient is likely to experience a wetness event. Bergman, at page 1, lines 34-39; page 2, lines 1-7; page 3, lines 9-17; page 4, lines 32-38, discloses the system inputs, sensors, processors, software and computer arranged to operate on a program that performs the substantially identical functions in the substantially identical manner, therefore the system of Bergman performs the claimed functional limitations in the same manner and thus meets the claim.

11. In the alternative, Bergman provides motivation for a characterising a wetness event. Panopoulos teaches a moisture monitoring system for monitoring wetness in absorbent articles (fig. 1) and at paragraphs [0192, 0222, page 29, column 2, item (h)] teaches the processor executes an algorithm to devise a mathematical model for characterising a wetness event in an absorbent article. therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the algorithms as taught by Panopoulos in the system of Bergman since Panopoulos states, at paragraph [0004-5], that the benefit of configuring the system with this design is that it permits caregivers to provide improved treatment for patients.

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Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

13. Collette et al (US 2005/0033250 A1); Bluteau (US 2003/0011479 A1); Pires (US 2005/0046578 A1); Nielson (US 6,246,330 B1); Fluyertas (US 5,902,296); Leung (US 4,507,121).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ginger T Chapman/
Examiner, Art Unit 3761
5/28/10

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/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772

Notice of References Cited	Application/Control No. 11/797,352		Applicant(s)/Patent Under Reexamination BERGMAN ET AL.	
	Examiner Ginger T. Chapman		Art Unit 3761	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-2005/0033250	02-2005	Collette et al.	604/361
*	B	US-2003/0011479	01-2003	Bluteau, Yves	340/573.5
*	C	US-2004/0100763	05-2004	Yuan et al.	361/685
*	D	US-2005/0046578	03-2005	Pires, Harold George	340/573.5
*	E	US-2004/0220538	11-2004	Panopoulos, Peter John	604/361
*	F	US-6,246,330	06-2001	Nielsen, Wyn Y.	340/604
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			


FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N	WO 96/14813	05-1996	PCT	Bergman, Frederick	A61F 5/48
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS


*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761


✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

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<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761


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<i>Index of Claims</i> 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761


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	Examiner Ginger T Chapman	Art Unit 3761

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BIB DATA SHEET

CONFIRMATION NO. 6338

SERIAL NUMBER	FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.		
11/797,352	05/02/2007	604	3761	P71951US0		
APPLICANTS Frederick Bergman, Caulfield, AUSTRALIA, Deceased; Ari Bergman, Caulfield, AUSTRALIA, Legal Representative; David Albert Barda, Docklands, AUSTRALIA; Daniel Weinstock, Caulfield South, AUSTRALIA; Remi Guibert, Mount Martha, AUSTRALIA; Maria C. Rodda, Mount Eliza, AUSTRALIA; Guy Eitzen, Wheelers Hill, AUSTRALIA;						
** CONTINUING DATA ***** This application is a CIP of PCT/AU05/01667 10/28/2005						
** FOREIGN APPLICATIONS ***** AUSTRALIA 2006902251 05/02/2006 AUSTRALIA 2004906315 11/03/2004						
** IF REQUIRED, FOREIGN FILING LICENSE GRANTED *** SMALL ENTITY ** 05/25/2007						
Foreign Priority claimed	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Met after Allowance	STATE OR COUNTRY	SHEETS DRAWINGS	TOTAL CLAIMS	INDEPENDENT CLAIMS
35 USC 119(a-d) conditions met	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		AUSTRALIA	11	79	7
Verified and	/GINGER T CHAPMAN/ Examiner's Signature	Initials				
Acknowledged						
ADDRESS JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004 UNITED STATES						
TITLE Incontinence management system and diaper						
FILING FEE RECEIVED 2440	FEES: Authority has been given in Paper No. _____ to charge/credit DEPOSIT ACCOUNT No. _____ for following:			<input type="checkbox"/> All Fees		
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Search Notes 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
	Examiner Ginger T Chapman	Art Unit 3761

SEARCHED			
Class	Subclass	Date	Examiner
604	361	5/28/2010	GC

SEARCH NOTES		
Search Notes	Date	Examiner
inventors' names search eDAN, EAST	5/28/2010	GC
EAST search attached	5/28/2010	GC

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner

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EAST Search History

EAST Search History**EAST Search History (Prior Art)**

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L2	4	L1 and (algorithm)	US-PGPUB; USPAT; FPRS; EPO; DERWENT	OR	OFF	2010/05/28 19:41
L1	14	(US-20070270774-\$ or US-20050033250-\$ or US-20040220538-\$ or US-20050046578-\$ or US-20030011479-\$).did. or (US-7522061-\$ or US- 7295125-\$ or US- 6246330-\$ or US- 5902296-\$ or US- 4507121-\$).did. or (WO- 2007128038-\$ or WO- 2006047815-\$ or WO- 9614813-\$).did. or (WO- 2007128038-\$).did.	US-PGPUB; USPAT; EPO; DERWENT	OR	OFF	2010/05/28 19:41
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S18	8	S17 and ((sensor\$) and ((user adj interface) or (GUI)))	US-PGPUB; USPAT; EPO; DERWENT	OR	OFF	2010/05/28 17:56
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S16	2	("20030011479").did.	US-PGPUB; DERWENT	OR	ON	2010/05/28 17:55
S15	3	("2003011479").did.	US-PGPUB; DERWENT	OR	ON	2010/05/28 17:54

EAST Search History

S14	9	("5902296" "4507121" "2003011479" "20050046578").did.	US-PGPUB; USPAT; DERWENT	OR	ON	2010/05/28 17:53
S13	8	S12 and ((user adj interface) or (GUI))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:49
S12	200	S10 and (sensor\$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:49
S11	17	S10 and (processor and sensor\$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:49
S10	486	604/361.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:48
S9	24	S2 or S3 or S4 or S5 or S6 or S7 or S8	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:45
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S7	2	eitzen-guy\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:44
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EAST Search History

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EAST Search History (Interference)

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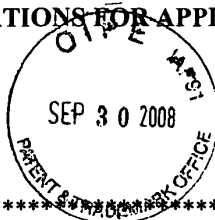
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JACOBSON HOLMAN PLLC
400 SEVENTH STREET, N.W.
WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P71951US0
SERIAL NO. 11/797,352
APPLICANT(S): BERGMAN et al.

GROUP ART UNIT: 3761
FILING DATE: May 2, 2007
TODAY'S DATE: September 30, 2008



U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,356,818	11/02/82	Macias et al.			
	AB	4,507,121	03/26/85	Leung			
	AC	4,539,559	09/03/85	Kelly et al.			
	AD	4,977,906	12/18/90	Di Scipio			
	AE	5,036,859	08/06/91	Brown			
	AF	5,264,830	11/23/93	Kline et al.			
	AG	5,416,469	05/16/95	Colling			
	AH	5,568,128	11/22/96	Nair			
	AI	5,537,095	07/16/96	Dick et al.			
	AJ	5,570,082	10/29/96	Mahgerefteh et al.			
	AK	5,557,263	09/17/96	Fisher et al.			
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FORM PTO-1449 (Modified)

Sheet 2 of 3

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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P71951US0
 SERIAL NO. 11/797,352
 APPLICANT(S): BERGMAN et al.

GROUP ART UNIT: 3761
 FILING DATE: May 2, 2007
 TODAY'S DATE: September 30, 2008

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	CC	1 063 624	12/27/00	Europe			
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FORM PTO-1449 (Modified)

Sheet 3 of 3

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 SERIAL NO. 11/797,352
 APPLICANT(S): BERGMAN et al.

GROUP ART UNIT: 3761
 FILING DATE: May 2, 2007
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EXAMINER	/Ginger Chapman/	DATE CONSIDERED	05/28/2010
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* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s)

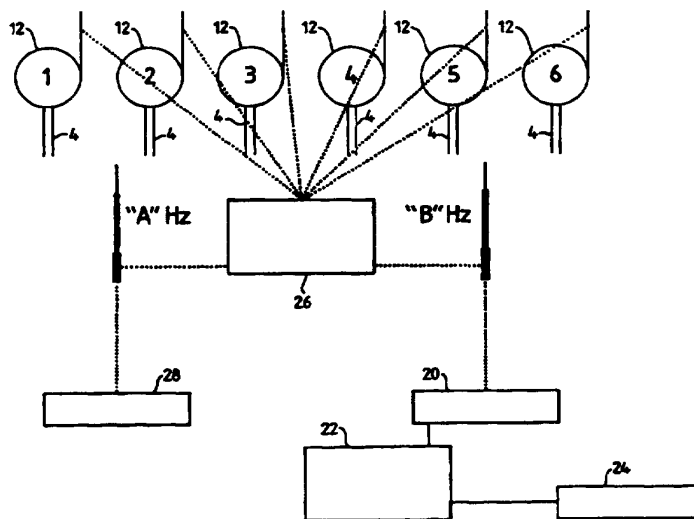
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61F 5/48	A1	(11) International Publication Number: WO 96/14813 (43) International Publication Date: 23 May 1996 (23.05.96)
(21) International Application Number: PCT/AU94/00697 (22) International Filing Date: 11 November 1994 (11.11.94) (71) Applicant (for all designated States except US): C & M INVESTMENT NOMINEES PTY. LTD. [AU/AU]; c/o Liddell Weight & Co., Chartered Accountants, 222 Kingsway, South Melbourne, VIC 3205 (AU). (72) Inventor; and (75) Inventor/Applicant (for US only): BERGMAN, Frederick [AU/AU]; 1 Lovell Street, East Hawthorn, VIC 3123 (AU). (74) Agents: HUNTSMAN, Peter, H. et al.; Davies Collison Cave, 1 Little Collins Street, Melbourne, VIC 3000 (AU).		(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LR, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD, SZ). Published With international search report.

(54) Title: INCONTINENCE MANAGEMENT SYSTEM



(57) Abstract

A monitor for use in hospitals, nursing homes and the like, to receive and record signals, from a plurality of sensors (4), of urinary and/or faecal incontinence in a corresponding number of patients to show when attention is required and to indicate, in respect of each patient, such pattern or regularity of such condition as may assist in the perception of the needs of that patient and, therefore, in the management of the condition and the efficiency of running of the establishment as a whole. The sensors (4) when activated in the presence of moisture send respective signals to a receive station (20) via a booster station (26). The time and sensor number(s) are recorded by a processor (22) and/or printer (24). A second signal may be transmitted by the booster (26) to a page (28) for staffing assistance.

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INCONTINENCE MANAGEMENT SYSTEM

This invention relates to an incontinence monitoring system and is particularly concerned with a system for the detection
5 monitoring and management of urinary, faecal and other forms of incontinence, in hospitals, nursing homes, geriatric institutions, private homes, gardens and suchlike places where, unchecked, such conditions can give rise to discomfort or at least embarrassment for the patient, an unpleasant
10 odour and environment for others in the vicinity, and considerable expenditure of human and financial resources due to the need for checking and, where necessary, changing and cleaning bed-linen and clothes.

15 Health regulations or recommendations may prescribe a maximum period e.g. 15 minutes for which a patient can be left in a wet state. In the past, in order to ensure both reasonable comfort for incontinents and compliance with prevailing regulations or normal practice it has generally been
20 necessary for nursing staff manually to check every patient at least once in the prescribed period. Quite apart from the unpleasantness, for nursing staff, or skin contact with patients' urine or faeces, such a regimen can be a severe strain on staff resources and an often unnecessary
25 interruption to patients' sleep.

It is an object of the invention to alleviate one or more of the above disadvantages.

30 According to the present invention there is provided an incontinence monitoring system for use in a hospital, nursing home or suchlike location, the system comprising a plurality of sensors and a monitor to receive and record signals from the sensors, each sensor being adapted to be associated with
35 a respective person and being responsive to urinary and/or faecal incontinence in that person, the monitor being capable of recording the time of onset of each incontinence condition and of indicating any regularity or pattern of incontinence in each said person.

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By detecting and recording, for a particular patient, any incontinence pattern rhythmicity or regularity, this can be used as a basis for predicting the likelihood of that patient being in a wet or dry state at a particular time, and
5 preferably forestalling such an event to enable the patient to receive appropriate and timely attention such as "toileting" e.g. by commode or bedpan.

The monitor may include a processor and a receiver adapted to
10 receive and discriminate between signals from the respective sensors.

Advantageously, the monitor includes display means for indicating said signals to an operator.

15 In a preferred embodiment the monitor includes a radio receiver and each sensor includes a transmitter adapted to emit a radio signal. The monitor may include a booster to boost the radio signals received thereby.

20 Advantageously, the monitor includes means for transmitting the signals or further signals responsive to the signals to one or more pager units.

25 Each sensor may comprise a flexible band comprising an insulating mounting for spaced conductor strips, the band being adapted to be located in a moisture-absorbent pad or garment to be worn by the patient so that at the onset of a wetting episode the moisture completes an electric circuit
30 between said strips and triggers the signal to the monitor.

More generally, in one embodiment, a sensor/transmitter for each patient (or other person to be monitored) may include an e.m.f. source such as a battery for a signal transmitter and
35 a sensor wired in circuit therewith and responsive to a condition the onset of which a warning is required.

The sensor may include two terminals between which is a

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moisture - receptive strip or pad of which the electrical conductivity is substantially zero in the normal or dry state but increases sharply when moistened by even a small amount of urine. The sensor therefore may act as a switch to pass
5 voltage/current to the signal transmitter, which may be in the form of a small wireless transmitter, at the onset of, for example, urination.

The signal can be transmitted as or via a coded radio signal
10 to a receiver which could be located in a nurses' station or central office. Associated with the receiver may be a microprocessor which interrogates the receiver (1) to determine or confirm that an alarm has been triggered and (2) to identify the relevant patient, with a computer (such as a
15 standard 386 with e.g. a 40 megabyte hard disk) arranged to operate on a program specially dedicated to the purpose of recording data for each of up to e.g. 48 patients.

The sensor band may be a re-usable strip attached to a nappy
20 or other moisture-absorbent pad suitably worn to detect the presence of urine. It may be secured using a piece of medical tape or placed in a pocket. Strips could be recovered by arrangement with a laundry service. If the garment to which it is attached is disposable, the strip
25 could be recovered by a staff member for cleaning "in house".

In order that the invention may be better understood reference will now be made, by way of example only, to the accompanying drawings which are to be considered as part of
30 this specification and read herewith. In the drawings:

Figure 1 is a diagram showing a practical embodiment of the invention in schematic form;

Figure 2 shows a detector band sensor and insertion tool for use with the invention as illustrated in Figure 1; and

35 Figure 3 shows a moisture absorbent pad capable of receiving a sensor by the means shown in Figure 2.

The practical embodiment of the invention as shown in the

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drawings, including the operation thereof, will now be described.

Figure 1 shows a monitor for only six patients. This is
5 merely for convenience of illustration. It is envisaged that
a much larger number could be monitored by the one device.

A master station 20 receives signals, via a suitable antenna,
from patient transmitters up to 250 metres distant. The
10 station may have an associated personal computer ("PC") 22
or, for example, may be connected direct to a printer 24.

Each patient has a code. The station may be powered from
240V AC mains supply reduced to 12V with battery back-up (not
15 shown) in case of mains failure. The battery may be
"trickle-charged" in known manner. Setter buttons may be
provided to record time, day, month, year and "re-set". If
a personal computer is used, such controls may not be
required if software allows for setting.

20 In lieu of or in addition to a PC monitor, a 3-4 digit Alpha
numeric light emitting diode ("LED") (not shown) may display
patient numbers and "low-battery" indication thereafter.
Simultaneous "alerts" may be sorted out by arranging for the
25 display to repeatedly "scroll" through alert numbers in
succession, dropping off each number as the relevant patient
is attended to. Where no PC is provided, the data may be
recorded by the directly-connected printer.

30 The master station 20 is operated by connecting a printer 24
or PC 22, setting the date and time, and noting and acting
upon "alerts" as they are recorded. Over a period of time,
for example 1 or 2 weeks, any pattern or regularity of
incontinence periods for a particular patient may be
35 identified from the recorded information, either manually or
using appropriate software, and the patient, or nursing
staff, may be arranged to anticipate an oncoming period of
incontinence.

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A booster, repeater and/or page unit 26 may be associated with the master station unit. It can be adjusted to receive one frequency e.g. 27 MHZ and boost the signal to the master station should circumstances so require. A different
5 frequency e.g. 150 MHZ could be used to transmit a signal to a pager 28 to call a staff member for assistance. A booster may boost the signal to the pager. Antennas and suitable connectors may be installed for both or all relevant frequencies.

10

Figure 2 illustrates an elongate sensor or detector band 4 and an applicator tool 5 for inserting band 4 into a nappy-type moisture absorptive pad 6 (Figure 3) adapted to be worn by the patient. Band 4 may include a pair of spaced
15 electrically conductive strips 7,8 of silver or other suitable material mounted on a length of polyester or other suitable insulating material. The top surface of each strip may be coated e.g. with carbon to prolong life of the strip. Strips 7, 8 are suitably positioned as to contact and to be
20 conductively bridged and thereby short-circuited by wetting of the pad 6 into which the band has been inserted, due care having been taken to ensure that the "conductive" side of the band i.e. the side to which strips 7, 8 are affixed, is in contact with the pad itself.

25

Band 4 has a forward end portion 9 receivable into spring clip 10 of tool 5. At the "rearward" end of band 4 is a connector element 11 whereby strips 7, 8 are placed in circuit with transmitter unit 12 (Figure 3).

30

The detector band (Figure 2) is fitted to the pad (Figure 3) as follows: the forward end portion 9 of a dry band 4 is inserted into spring clip 10 of the applicator tool. Pointed end 13 at the same end of the tool as clip 10 is used to
35 puncture an eternal waterproof plastics or like lining 14 of pad 6 about 60 to 80 mm in from the edge as shown in Figure 3. The tool 5 with band 4 in train is then pushed inwards along the centre line of pad 6, just separating the lining

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from the absorbent material with the strips 7, 8 facing away from the lining and towards the absorbent material.

When the band is fully inserted, connector 11 is held
5 independently of the tool which is pushed further in so as to disengage band 4 from clip 10.

Tool 5 is then turned 180° about its longitudinal axis so that it can be withdrawn without the clip 6 catching the
10 band. Band 4 now having been suitably located with conductive strips 7, 8 thereof facing the absorbent material of pad 6, tool 5 is withdrawn, leaving band 4 in place.

Transmitter 12 can be fitted to pad 6 using chrome clasps 16,
15 as shown in Figure 3, with appropriate electrical connections to strips 7, 8 shown schematically at 17 via connector element 11.

The pad/transmitter assembly is now ready for fitting to the
20 patient.

Rather than being inserted and attached to pads such as 6, a sensor band or unit could be incorporated into e.g. a disposable paper garment or an underblanket or mat such as by
25 printing or stitching, with suitable means for connection to a separate transmitter.

The transmitter 12 should be as small as possible. An LED may show when it is activated and may stay on until band 4 is
30 removed from a moisture zone thereby concluding an "episode".

The transmitter may be powered by a re-chargeable NiCd battery.

35 A low power battery signal may report to both master display and pager (Figure 1).

The transmitter may be operated as follows: open the

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transmitter unit 12; select a patient code number e.g. Mr Smith 007. (If a computer is used the patient code is keyed in); install the battery, close the transmitter unit, and attach unit 12 to pad 6 as already described with strips 7, 8 suitably connected.

When an "episode" occurs the transmitter LED illuminates and a signal is transmitted to the booster station 26. The booster repeats the signal, at frequency "B" (see Figure 1) to the master station 20 which displays "007" - for the duration of the episode. The printer 24 records "007" on a date/time basis as may the PC 22.

The booster 26 sends also a signal of frequency "A" to the pager 28 to alert the nurse. The signal identifies "007" alert, and optionally also the time and date, on the pager display. The nurse acknowledge the message on the pager. Only one signal need be sent to the pager.

The nurse attends to the patient, disconnects the transmitter and fits a new absorbent pad. The transmitter is re-connected ready for the next episode. The pager memory can now be cleared, because data of the episode will have been recorded by the master station printer and/or computer.

It will clear that especially in the case of bed-ridden patients, rather than by radio, signals could be sent through an electric wiring system from a transmitter at the bedside and only a sensor/pad component connected to the wiring need be attached to the patient.

In some cases signals could be sent by wire (as distinct from radio) through the same or similar system to that used e.g. with a nurse call button.

Also the invention can evidently be applied to the unconscious, semi conscious, paralyzed, part-paralyzed or confused, or any other patient who may be unable to initiate

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a signal.

- Furthermore it will be clear that the invention, in its "radio" form, is applicable to patients who are free to move around and even outside a building. Appropriate circuitry may provide an indication of the wearer's location (distance and direction) relative to a datum point, including an alarm should the wearer stray beyond a prescribed boundary.
- 10 Those skilled in the art will appreciate that the invention described herein is susceptible to variations and modifications other than those specifically described. It is to be understood that the invention includes all such variations and modifications which fall within the its spirit and scope. The invention also includes all of the steps, features, compositions and compounds referred to or indicated in this specification, individually or collectively, and any and all combinations of any two or more of said steps or features. In particular it will be appreciated that a further aspect of the invention may be directed to all or any of the described features of the sensor, pad, mat and/or locating tool.

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CLAIMS:-

1. An incontinence monitoring system for use in a hospital,
nursing home or suchlike location, the system comprising a
5 plurality of sensors and a monitor to receive and record
signals from the sensors, each sensor being adapted to be
associated with a respective person and being responsive to
urinary and/or faecal incontinence in that person, the
monitor being capable of recording the time of onset of each
10 incontinence condition and of indicating any regularity or
pattern of incontinence in each said person.
2. A monitoring system as claimed in claim 1 wherein the
monitor includes a processor and a receiver adapted to
15 receive and discriminate between signals from the respective
sensors.
3. A monitoring system as claimed in claim 1 wherein the
monitor includes display means for indicating said signals to
20 an operator.
4. A monitoring system as claimed in claim 3 wherein the
display means include an alpha numeric LED capable of
displaying code indicia for each said person.
25
5. A monitoring system as claimed in claim 1 wherein the
monitor includes a radio receiver and each sensor includes a
transmitter adapted to emit a radio signal.
- 30 6. A monitoring system as claimed in claim 5 wherein the
monitor includes a booster to boost the radio signals
received thereby.
7. A monitoring system as claimed in claim 1 wherein the
35 monitor includes means for transmitting the signals or
further signals responsive to the signals to one or more
pager units.

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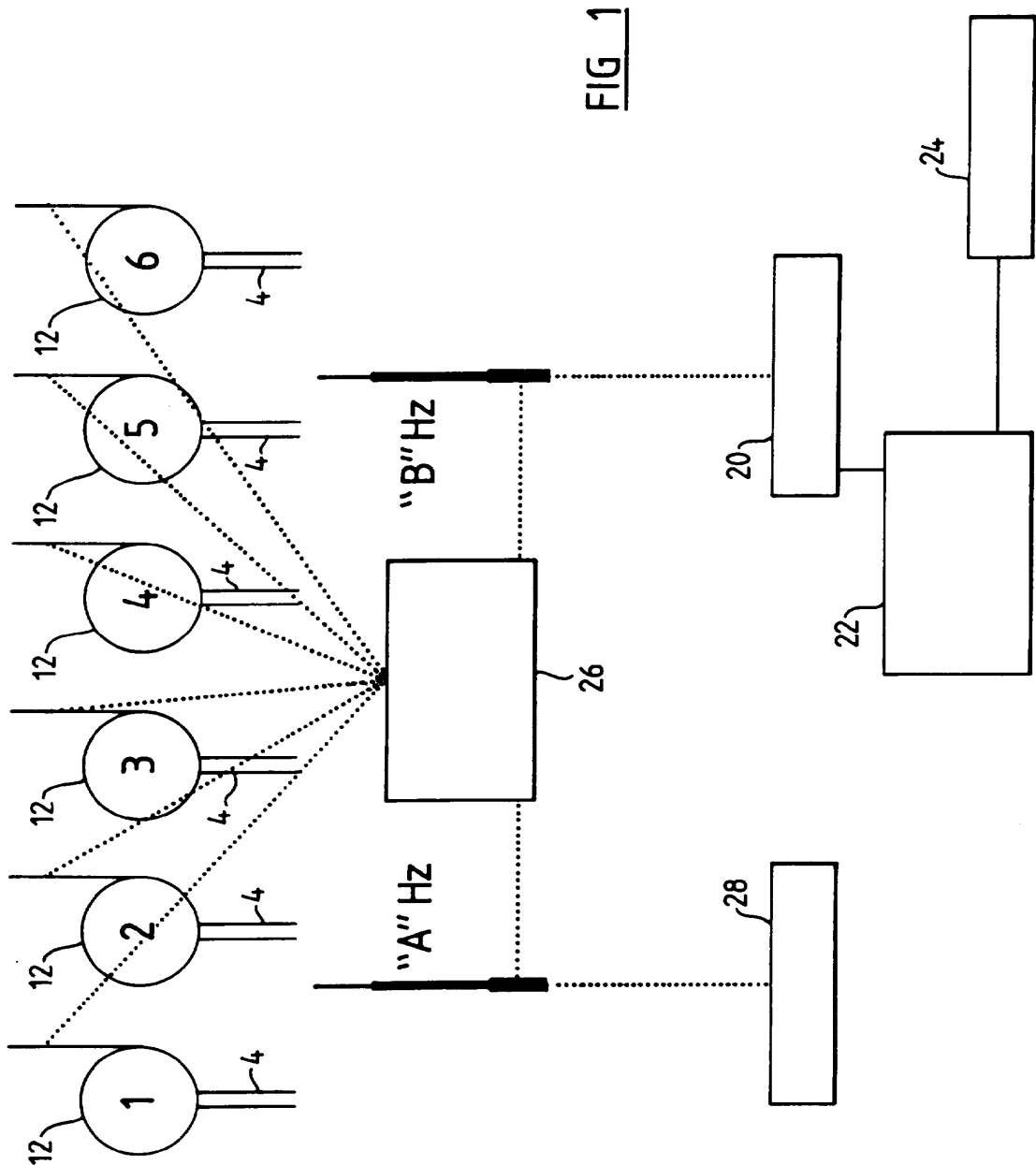
- 10 -

8. A monitoring system as claimed in claim 1 wherein each sensor is a flexible band comprising an insulating mounting for spaced conductor strips, the band being adapted to be located in a moisture-absorbent pad or garment to be worn by
5 the patient so that at the onset of a wetting episode the moisture completes an electric circuit between said strips and triggers the signal to the monitor.

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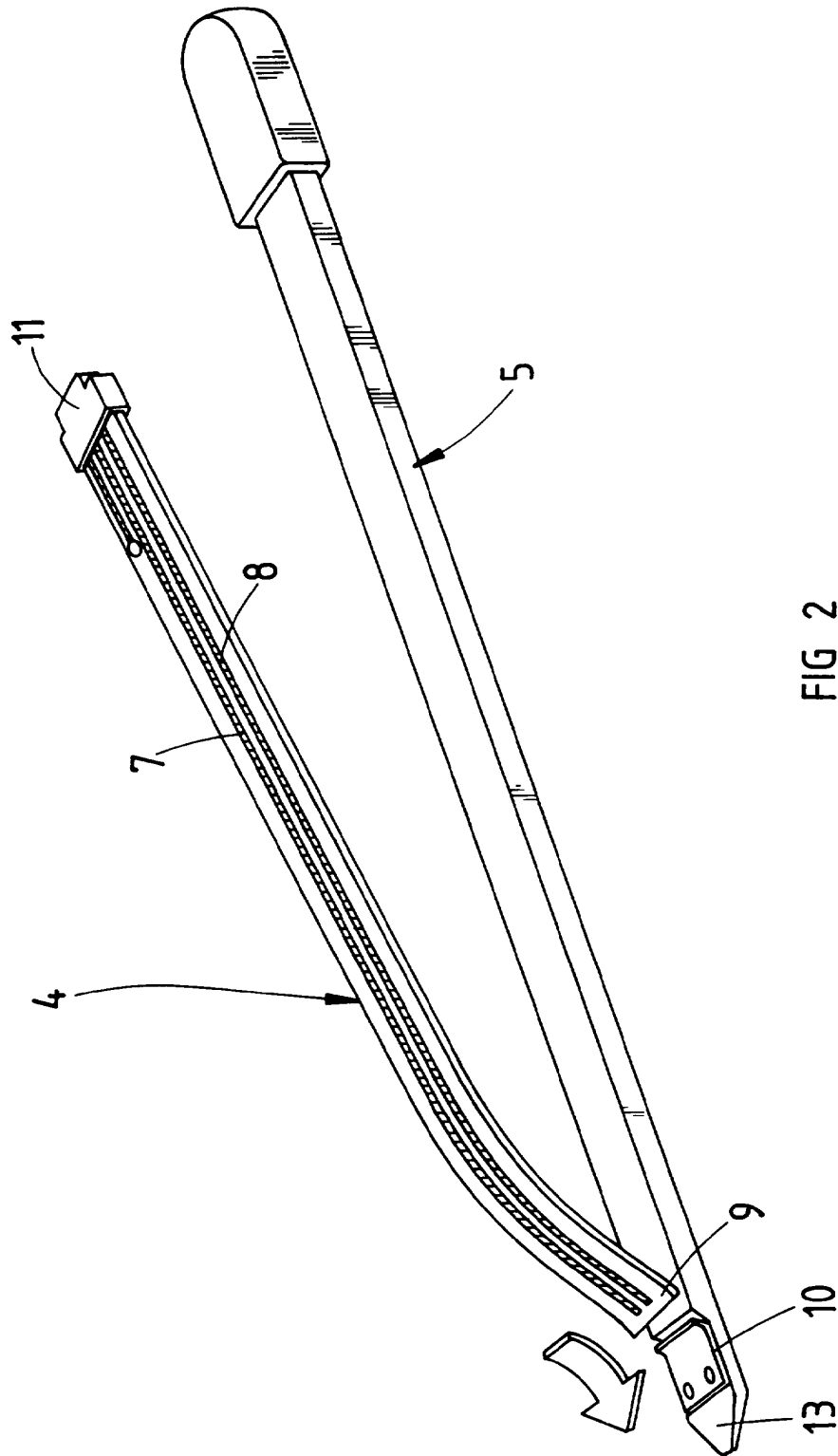
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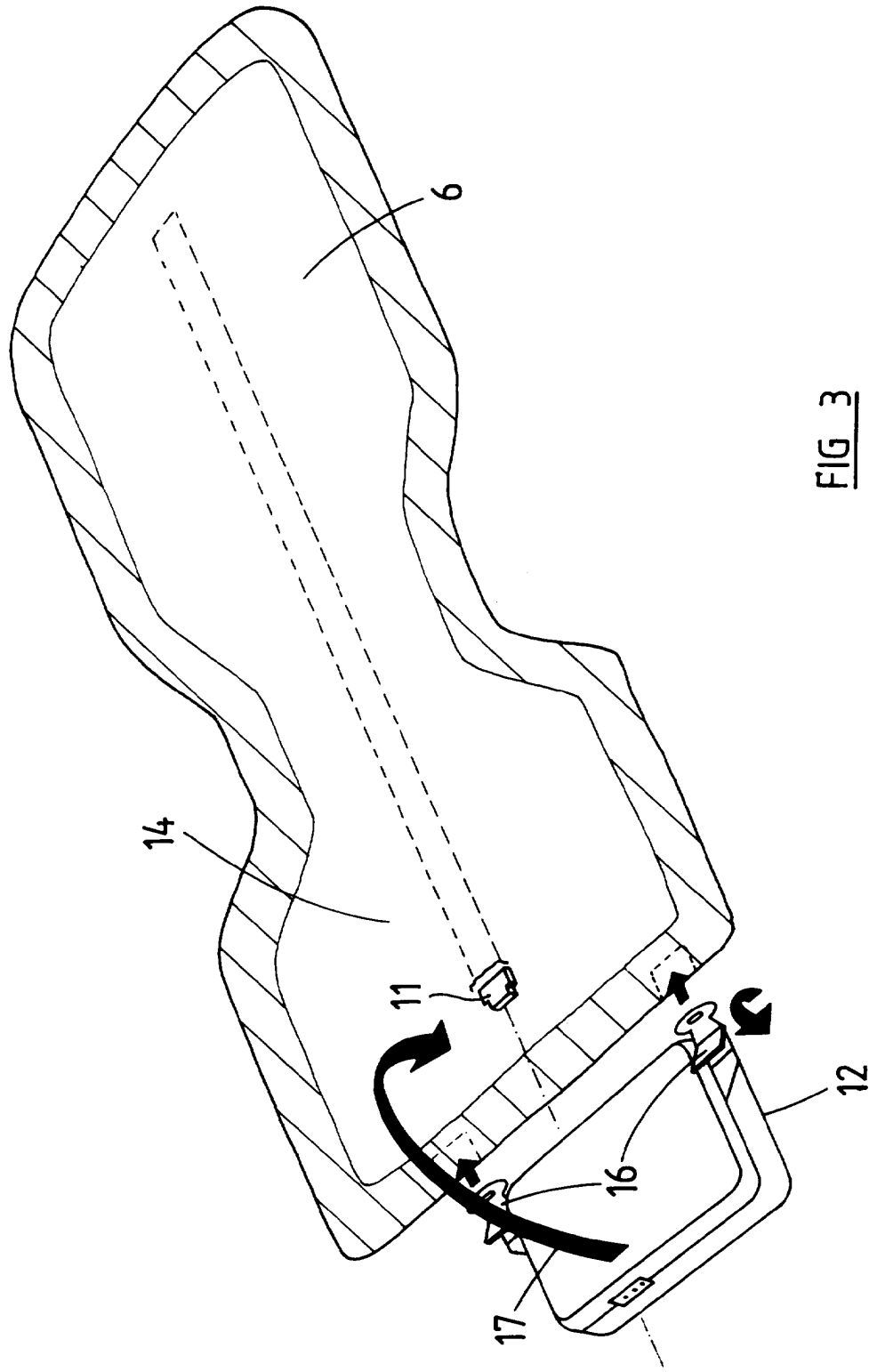
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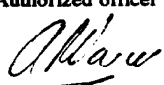
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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 94/00697

A. CLASSIFICATION OF SUBJECT MATTER Int. Cl. ⁶ A61F 5/48 According to International Patent Classification (IPC) or to both national classification and IPC												
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC : A61F 5,48, 5/44, A61F 13/42, 13/44 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched AU : IPC as above Electronic data base consulted during the international search (name of data base, and where practicable, search terms used) JAPIO DERWENT : monitor: or sens: or alarm												
C. DOCUMENTS CONSIDERED TO BE RELEVANT												
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.										
Y	US,A, 5137033 (NORTON) 11 August 1992 (11.08.92) See col. 3 lines 55-66											
X Y	US,A, 5074317 (BONDELL et al) 24 December 1991 (24.12.91) See col. 6 lines 15-27											
A	EP,A, 270048 (STEGAT) 8 June 1988 (08.06.88)											
A	WO, 86/04710 (RADAKOVIC) 14 August 1986 (14.08.86)											
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input checked="" type="checkbox"/> See patent family annex.												
* Special categories of cited documents : <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier document but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
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"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family											
"P" document published prior to the international filing date but later than the priority date claimed												
Date of the actual completion of the international search 21 February 1995 (21.02.95)		Date of mailing of the international search report 24 Feb 1995 (24.02.95)										
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No. 06 2853929		Authorized officer  A. DAVIES Telephone No. (06) 2832072										

INTERNATIONAL SEARCH REPORTInternational application No.
PCT/AU 94/00697

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate of the relevant passages	Relevant to Claim No.
A	FR, 2529080 (LERNOULD) 30 December 1983 (30.12.83)	
A	DE,A1, 2807538 (SCHLENKE) 23 August 1979 (23.08.79)	

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JA0827

INTERNATIONAL SEARCH REPORT
 Information on patent family members

International application No.
PCT/AU 94/00697

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member		
US	5137033				
US	5074317				
EP	270048	DE	3640900		
WO	86/04710	AU	53923/86	CH	676060
		EP	211874	GB	8606416
FR	2529080				
DE	2807538				
END OF ANNEX					



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Confirmation No.: 6338
Frederick BERGMAN et al.	Attorney Docket No.: P71951US0
Serial No. 11/797,352	Group Art Unit: 3761
Filed: May 2, 2007	Examiner: Ginger T. CHAPMAN
For: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER	

AMENDMENT UNDER 37 C.F.R. 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Official Action mailed June 8, 2010, please amend the above-identified application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 13 of this paper.

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Amendments to the Claims:

The listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Currently amended) A moisture monitoring system for monitoring wetness in one or more absorbent articles, the system including:

an input for receiving one or more sensor signals indicative of a presence of wetness in an absorbent article;

~~a processor for processing the one or more sensor signals and for performing an analysis of the signals to characterise wetness events occurring in an absorbent article;~~
and

user interface for communicating with a user of the system;

wherein the processor executes an algorithm to analyze the one or more sensor signals by applying the one or more received sensor signals to a pre-determined mathematical model to characterize a wetness event in an absorbent article; and

wherein the system has devised the pre-determined mathematical model using sensor signal data previously received by the system, the mathematical model representing a relationship between one or more variables obtainable from the received sensor signals and a characteristic used to characterise a wetness event.

2. (Cancelled)

3. (Currently amended) A moisture monitoring system according to claim 1 wherein the processor executes the ~~an~~ algorithm to ~~perform the analysis and wherein the algorithm applies~~ uses the sensor signals and a pre-determined mathematical model to characterise a wetness event in an absorbent article by determining one or more of:

- (i) an estimated volume of exudate in a wetness event; and
- (ii) the nature of exudate in a wetness event.

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4. (Currently amended) A moisture monitoring system according to claim 1 wherein the ~~system processor~~ uses the received sensor signals and/or variables derived from the received sensor signals to derive one or more parameters suitable for use in the a mathematical model ~~for characterising a wetness event~~.

5. (Currently amended) A moisture monitoring system according to claim 4 ~~3~~ wherein the ~~system algorithm~~ applies variables derived from the one or more received sensor signals to optimize the a pre-determined mathematical model for characterizing to ~~characterise~~ a wetness event.

6. (Currently amended) A moisture monitoring system according to claim 1 ~~3~~ wherein the one or more sensor signals are indicative of one or more of:

- (i) conductivity of the exudate;
- (ii) temperature of the exudate;
- (iii) location of the exudate;
- (iv) pH of the exudate;
- (v) pressure within the absorbent article;
- (vi) odour within the absorbent article;
- (vii) presence of a gas in the absorbent article;
- (viii) presence of blood and/or a biological marker and/or a ~~or~~ chemical marker

in the exudate.

7. (Currently amended) A moisture monitoring system according to claim 1 ~~[[4]]~~ wherein variables derived from the sensor signals are selected from the group including:

- (i) area under a sensor signal curve;
- (ii) highest sensor signal value in a predetermined time period;
- (iii) maximum value of a leading edge of the sensor signal;
- (iv) rate of decay of sensor signal after a leading edge;
- (v) a volume estimated in a previous wetness event;
- (vi) time of onset of a wetness event;

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- (vii) time of termination of a wetness event; and
- (viii) duration of a wetness event;
- (ix) time of day of a wetness event; and
- (x) time elapsed since last wetness event.

8. (Original) A moisture monitoring system according to claim 1 wherein the processor is configured to determine one or more of:

- (a) a likelihood of an imminent wetness event;
- (b) an estimate of when a wetness event is likely to occur;
- (c) an estimate of a degree of fullness of an absorbent article; and
- (d) an estimate of when an absorbent article is likely to reach its absorbent capacity.

9. (Previously presented) A moisture monitoring system according to claim 1, wherein the user interface includes a wireless transmitter configured to transmit a signal to a user of the system to indicate that a predetermined volume of wetness has been detected in an absorbent article.

10. (Currently amended) A moisture monitoring system according to claim 1 wherein the system is configurable ~~processor is configured~~ to provide a toileting or voiding diary.

11. (Currently amended) A moisture monitoring system according to claim 1 [[3]] wherein the system is configurable ~~processor is configured~~ to derive a toileting or voiding schedule for an individual, based on wetness events monitored using the monitoring system.

12. (Original) A moisture monitoring system according to claim 11 wherein the system is configured to predict, based on a derived toileting or voiding schedule, when an individual is likely to experience a wetness event which meets pre-defined criteria for manual checking.

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13. (Original) A moisture monitoring system according to claim 1 wherein the system is further adapted to communicate automatically, an alert to a carer when one or more pre-defined criteria for manual checking are satisfied.

14. (Currently amended) A moisture monitoring system according to claim 1 wherein the system processor is configured to classify a possible form of incontinence suffered by a patient monitored by the system, the form of incontinence being selected from the group including urinary, fecal, dribble, stress, overflow, urge, mixed urinary (MUI), total and functional incontinence.

15. (Currently amended) A moisture monitoring system according to claim 1 wherein the system processor is configured to perform one of recognizing and predicting the occurrence of lingering wetness in a region of an absorbent article.

16. (Original) A moisture monitoring system according to claim 1 wherein the processor is affixable to a sensor, an absorbent article or to a garment worn by a wearer of an absorbent article.

17. (Original) A moisture monitoring system according to claim 1 wherein the processor is incorporated into a central monitoring station adapted to receive sensor signals from a plurality of sensors associated with one or more absorbent articles.

18. (Currently amended) A moisture monitoring system according claim 1 wherein the processor includes ~~including~~ a pre-processor associated with a sensor of an absorbent article.

19. (Currently amended) A moisture monitoring system according to claim 3, adapted to reconfigure the ~~one or more~~ mathematical model ~~models~~ for use with one or more of a particular individual being monitored, a different sensor type and a different absorbent article type, by:

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for a training period using the particular individual, the different sensor type or the different absorbent article type, monitoring wetness at regular intervals by obtaining sensor signals and obtaining observation data; and

reconfiguring the mathematical model so that there is satisfactory correlation between wetness estimates produced using the sensor signals and the reconfigured mathematical model, and wetness observations from the observation data obtained during the training period.

20. (Original) A moisture monitoring system according to claim 19 wherein reconfiguring a mathematical model involves determining one or more new parameters for the mathematical model.

21. (Original) A moisture monitoring system according to claim 19 wherein reconfiguring a mathematical model involves application of a linear regression algorithm.

22. (Original) A moisture monitoring system according to claim 19 wherein the observation data includes measurements indicating an amount of wetness in the absorbent article and time of measurement.

23. (Original) A moisture monitoring system according to claim 19 wherein the observation data includes one or more of:

demographic information; and
patient information.

24. (Previously presented) A moisture monitoring system according to claim 1 further including one or more sensors for use with an absorbent article being monitored for wetness, the sensor including a plurality of sensor elements arranged in a pattern which provides an improved ability to detect wetness.

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25. (Previously presented) A moisture monitoring system according to claim 24 wherein the sensor elements are arranged in a pattern in which there are more sensor elements in regions having higher propensity for variable moisture or temperature.

26. (Previously presented) A moisture monitoring system according to claim 24 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements extend beyond an edge thereof.

27. (Previously presented) A moisture monitoring system according to claim 26 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements extend beyond a front edge thereof.

28. (Previously presented) A moisture monitoring system according to claim 24 further including, for each absorbent article being monitored, a signal receiver unit and a connector for connecting sensor elements associated with an absorbent article to an associated signal receiver unit.

29. (Previously presented) A moisture monitoring system according to claim 24 further including, for each absorbent article being monitored, a cover layer over the sensor elements, the cover layer extending beyond an edge of the absorbent article and including means for enclosing a signal receiver unit attachable to one or more of the sensor elements.

30. (Previously presented) A moisture monitoring system according to claim 24 wherein, when applied to or incorporated into an absorbent article, one or more sensor elements are arranged for connection to a signal receiver unit outside the absorbent article.

31. (Previously presented) A moisture monitoring system according to claim 28 wherein the signal receiver unit includes storage means for storing sensor signals collected over a period of time.

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32. (Previously presented) A moisture monitoring system according to claim 28 wherein the signal receiver unit includes means for receiving data relating to a patient's toileting activities.

33. (Previously presented) A moisture monitoring system according to claim 24 wherein the pattern includes sensor elements positioned toward the sides of the absorbent article, near an opening for receiving a leg of the wearer.

34. (Previously presented) A moisture monitoring system according claim 24 wherein the pattern includes sensor elements located at two or more depths of the absorbent article.

35. (Previously presented) A moisture monitoring system according to claim 24 wherein the sensor includes a sensor substrate, the sensor substrate having one or more channels arranged between adjacent elements of the sensor.

36. (Previously presented) A moisture monitoring system according to claim 35 for use with an absorbent article having super absorbent material arranged in the article so as to draw fluid from the one or more channels in the sensor substrate.

37. (Previously presented) A moisture monitoring system according to claim 24 wherein the sensor is provided on a flexible substrate affixable, by adhesive or other means, to an absorbent article wearable by a user.

38. (Previously presented) A moisture monitoring system according to claim 24 wherein the sensor elements detect wetness at various identifiable locations with respect to the absorbent article, the locations selected from the group including:

- (a) toward the front of the absorbent article;
- (b) toward the rear of the absorbent article;
- (c) toward a side of the absorbent article; and
- (d) substantially centrally of the absorbent article.

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39. (Previously presented) A moisture monitoring system according to claim 24 wherein the pattern of sensor elements facilitates improved detection of moisture from a user in a range of positions including standing, sitting, lying prone, lying supine and lying on the side.

40. (Previously presented) A moisture monitoring system according to claim 24 wherein the sensor elements are arranged to detect spread of moisture from a wetness event in two or more directions.

41. (Previously presented) A moisture monitoring system according to claim 24 wherein the sensor pattern includes one or more of:

- elongate sensor elements;
- sensor elements arranged in a grid; and
- an array of sensor element dots.

42. (Previously presented) A moisture monitoring system according to claim 24 wherein the sensor includes sensor elements for detecting one or more of electrical conductivity, temperature, pressure, pH, odour, gas and presence of a biological or chemical marker in exudate and location of exudate.

43 – 56 (Cancelled)

57. (Previously presented) A diaper for a person to wear, for use with the moisture monitoring system of claim 1 wherein said diaper includes a sleeve for the insertion of a diagnostic strip.

58. (Original) A diaper according to claim 57 characterised in that said sleeve is located on said diaper close to, in use, the pubic area of a wearer.

59. (Original) A diaper according to claim 57, characterised in that said diaper has means designed to direct fluids excreted by said person, to said sleeve.

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60. (Original) A diaper according to claim 57, characterised in that said sleeve is provided with a V-shaped notch to facilitate the insertion of a diagnostic strip.

61. (Original) A diaper according to claim 57, characterised in that said sleeve is attachable to said diaper by adhesive material.

62. (Original) A diaper according to claim 59, characterised in that said means designed to direct fluids excreted by said person, to said sleeve, is constituted by pores and/or channels.

63. (Original) A diaper according to claim 62, characterised in that said pores and/or channels are located around the periphery of said sleeve.

64. (Original) A diaper according to claim 57, characterised in that sleeve is adapted to retain a predetermined amount of exudate to facilitate contact of said exudate with said strip.

65. (Previously presented) A diaper for a person to wear, for use with the moisture monitoring system of claim 1 wherein said diaper is provided with a plurality of sensors at different locations in said diaper.

66. (Original) A diaper according to claim 65, characterised in that said sensors are wetness sensors.

67. (Original) A diaper according to claim 66, characterised in that said sensors are adapted to permit the estimation of the volume of exudate flowing from the patient in real time.

68. (Currently amended) A diaper according to claim 67, characterised in that the volume of exudate passed by the person wearing said diaper, preferably in a unit of time,

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is established using the a-mathematical model and computed by using such factors as the distance between said sensors, the rate of transfer of moisture between said sensors, and the absorption properties of the materials used, such as polymer fibres, natural fibres and combinations of polymer fibres and natural fibres.

69. (Currently amended) A diaper according to claim ~~68~~65, characterised in that data from said sensors is transmitted using radio technology, and in that said data is processed using software running the aforementioned mathematical model.

70. (Original) A diaper according to claim 65, characterised in that each of said sensors is constituted by conductive inks.

71. (Original) A diaper according to claim 65, characterised in that the spacing of said sensors is at different thicknesses in material forming at least a part of said diaper.

72. (Currently amended) A pad for use with a diaper, and the moisture monitoring system of claim 1, wherein said pad is being associated with transmitting means, for transmitting signals representative of an aspect of fluids absorbed by said pad, to a remote location.

73. (Original) A diaper according to claim 72, characterised in that said pad includes a chamber for collection of said fluids.

74. (Original) A diaper according to claim 73, characterised in that said chamber is removable.

75 – 79 (Cancelled)

80. (Previously presented) A moisture monitoring system according to claim 1 configurable to adapt a mathematical model to characterise a wetness event in an absorbent article being monitored using one or more of a new sensor type, new sensor

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element and a new type of absorbent article not previously used with the moisture monitoring system.

81. (Previously presented) A moisture monitoring system according to claim 1 wherein the processor is configured to receive automatically data pertaining to known features of an absorbent article selected from a group including: volume capacity, type, brand and location of sensors embedded therein.

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REMARKS

In this Amendment, Applicant has cancelled Claim 2 without prejudice or disclaimer and amended Claims 1, 3 – 7, 10 – 11, 14 – 15, 18 – 19, 68 – 69 and 72 to overcome the rejections and specify the embodiments of the present invention. The support for the amendments to the claims can be found throughout the specification. It is respectfully submitted that no new matter has been introduced by the amended claims. Applicant respectfully submits that Claim 1 as amended is generic to each of species 2 to 5 identified in the Examiner's Office Action of 28 April 2010. Once Claim 1 is allowable, claims directed to other species should also be considered and allowed. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

REJECTIONS UNDER 35 U.S.C. § 102:

Claim 1 has been rejected under 35 U.S.C. § 102 (b) as allegedly being anticipated by Bergan et al. (WO 96/14813).

Applicant traverses the rejection and respectfully submits that the present-claimed invention is not anticipated by the cited reference. To anticipate a claim, the reference must teach each and every element of the claim. Bergan does not disclose all the features of Claim 1 as amended.

Therefore, the amended and newly presented claims are not anticipated by Bergan and the rejection under 35 U.S.C. § 102 (b) has been overcome. Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 (b) is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103:

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Claim 2 has been rejected under 35 U.S.C. § 103 as allegedly being unpatentable over Bergan in view of Panopoulos (US 2004/0220538).

Applicant traverses the rejection and respectfully submits that the embodiments of present-claimed invention are not obvious over cited references.

Claim 2 of the instant application recites that the processing mean executes an algorithm “*to devise a mathematical model for characterizing a wetness event in a pad*”. The Examiner is of the view that this feature is obvious because algorithms are known for calculation and data processing functions. The Examiner goes on to state that “*the instant algorithm characterizes wetness events such as nature of exudates (either urinary or fecal), volume of discharge, and applies the sensor signals to predict when a patient is likely to experience a wetness event*”. Applicant respectfully notes that this statement is erroneous. Claim 1 as amended, recites that:

- (i) the processing means executes an algorithm to analyze the one or more sensor signals by applying the one or more received sensor signals to a pre-determined mathematical model to characterize a wetness event in an absorbent article;
- (ii) wherein the mathematical model has been pre-determined by the system based on previously received sensor signal data, the mathematical model representing a relationship between one or more variables obtainable from the received sensor signals and a characteristic used to characterize a wetness event.

In the instant application, the pre-determined mathematical model devised by the system executing the algorithm gives rise to a mathematical equation or plurality of equations which together, describe mathematically the behavior of the absorbent article and the wetness events occurring in it, based on sensor signals that have been received previously by the system. The set of equations (i.e. mathematical model) determined by the system can be solved by the processing means executing an algorithm to analyze the signals by applying the one or more received sensor signals to the mathematical model to

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characterize a wetness event occurring in the absorbent article by determining e.g. volume of the event.

Applicant respectfully urges the Examiner to consider that a system which (a) employs a mathematical model which has been pre-determined based on data previously received by that system and (b) applies that mathematical model to sensor signals to characterize a wetness event is not the same thing as a system which uses an algorithm (i.e. set of instructions) to merely transpose a received sensor signal (e.g. a voltage) to a characteristic value (e.g. indicating wetness or dryness) using a look up table or the like, rather than using a complex mathematical model which is derived based on signals received from the sensors which themselves form part of the inventive system. This is a significant development in the instant invention and deviation from what is disclosed in Bergman.

Applicant respectfully disagrees with the Office's assertion that Bergman *"discloses the system inputs, sensors, processors, software and computer arranged to operate on a program that performs the substantially identical functions in the substantially identical manner, therefore the system of Bergman performs the claimed functional limitations in the same matter and thus meets the claim"*. Applicant respectfully notes that the rejection in item 10 of the Office Action is completely silent as to mathematical models employed by the system of Bergman and derivation of a mathematical model using sensor signals previously obtained by the system. Applicant has reviewed the disclosure of Bergman and did not find any reference to the use of mathematical models or use of previously obtained sensor signals to devise a mathematical model or an algorithm which uses a mathematical model for determining or characterizing a wetness event. Accordingly, Applicant does not see how the disclosure of Bergman can be considered to teach the functions achieved by the system of claim 1 as amended herewith, whether that be in an identical manner or a substantially identical manner. Should the Examiner disagree, Applicant respectfully requests that the Examiner specify the location of the reference within Bergman pointing to the derivation of a mathematical model in any further Office Action.

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Further, Applicant submits that one of ordinary skill in the art, having the background knowledge conveyed by the disclosure of Bergman, would not have considered it is an obvious feature when the processing means executes an algorithm to analyze signals by applying received sensor signals to a mathematical model that has been pre-determined by the system based on previously received sensor signals.

Turning to rejection item 11, the Examiner indicated under 35 USC §103(a) in the alternative, that Bergman provides motivation for characterizing a wetness event. The Examiner does not provide a reference for the location in Bergman of this motivation. Nevertheless, the Examiner goes on to assert that Panopoulos teaches a moisture monitoring system for monitoring wetness in absorbent articles and,

“At paragraphs [0192, 0222, page 29, column 2, item (h)] teaches the processor executes an algorithm to devise a mathematical model for characterizing a wetness event in an absorbent article. [T]herefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the algorithms as taught by Panopoulos in the system of Bergman since Panopoulos states, at paragraph [0004-5], that the benefit of configuring the system with this design is that it permits care givers to provide improved treatment for patients”.

Applicant notes that the first cited passage refers to “*Calibration ROM For Each Transducer*” identified by reference numeral 58 in figures 12 and 13. These figures depict a “*circuit card unit*” of the invention in Panopoulos. As stated in paragraph [0192], the calibration read-only-memory (ROM) contains the calibration code algorithm to convert the conditioned signal data to usable data, such as specific temperature or humidity units. The statement at paragraph [0222] is substantially identical to the statement in paragraph [0192]. The data are then stored in RAM and used to set off a set of alarms or appear on a LCD read out on the circuit card unit.

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The algorithm stored in ROM, according to Panopoulos, performs the specific function of *converting* conditioned (i.e. digitized) signal data to usable data. Thus, according to Panopoulos, the algorithm does nothing more than applying a conversion factor or interrogating a look up table to ascertain the usable data from the conditioned signal data. Whilst it may be the case that the conversion is established by applying a mathematical equation, Applicant notes that any such equation is pre-programmed into the calibration ROM. There is no teaching or suggestion in Panopoulos that a mathematical model is determined *by the system*, based on previously received sensor data.

This is contrary to the instant invention as it is recited in claim 1 where the processing means executes an algorithm which uses the sensor signal data and a pre-determined mathematical model which has been pre-determined by the system using data previously received by the system. The mathematical model is, for example, a mathematical equation or plurality of equations which can be solved to characterize a wetness event occurring in an absorbent article.

The next passage cited by the Examiner on page 29, column 2, item (h) discloses,

“algorithm(s) to identify what sensors discover and report it to the caregivers on the ‘Nurse Remote Wand’ and/or directly to wireless receiver links to computer data base(s); and further, algorithm(s) to report concentration(s) of item(s) sensed by sensor(s) in the diaper(s);”

The disclosure on page 29 goes no closer to identifying a mathematical model which is derived or devised by the system and applied to the sensor signal.

Applicant notes that the problem being solved by Panopoulos is different from the problem being solved by the instant invention. As stated by the Examiner, Panopoulos aims to provide a system that permits caregivers to provide improved treatment for patients (Office Action item 11 on page 4 last line). As stated in the background, the

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invention of Panopoulos aims to create “*a more sanitary environment where caregivers will know immediately when urine and/or feces have been expelled to correct the condition*” [0006]. Panopoulos specifically states that a problem with conventional diapers are that they “*do not provide means to eliminate prolonged contact with urine or fecal matter and the bacteria and/or the viruses that these contaminants have in infants, toddlers, children, and older adults who may have weak immune systems*” [0014].

In addition, at [0019], the application provides “*means to communicate to caregivers that a child or an adult under care may have urinated or expelled matter into their diapers, so the caregiver may change them to create a more sanitary condition as immediately as possible to comfort the patient ...*”. Further, at [0021] “*by alerting caregivers of a wetness condition when urination and/or fecal expulsion occurs, a caregiver may change a diaper immediately thus minimizing contact of these contaminants with the skin immediately, thus eliminating diaper rash and other diseases ...*”. Thus, the objective in Panopoulos is to provide a system which provides an **immediate** alert to caregivers as soon as urinary or fecal exudate is detected in a diaper. Panopoulos achieves this objective by providing a system that enables caregivers to receive an alert **immediately** either by visible, auditory or other means, e.g. on the Nurse Remote Wand or on a circuit card unit attached to the diaper.

This is contrary to the instant invention where sensor signals detecting wetness in incontinence garments are processed to provide more detailed information about the wetness event and not merely identify when the event has occurred for alerting a caregiver. For instance, the instant invention is directed to a system which, for example, provides a prediction indicating a likelihood of an imminent wetness event, an estimation of when a wetness event is likely to occur, an estimation of a degree of fullness of an absorbent article, and/or an estimate of when an absorbent article is likely to reach its absorbent capacity (specification page 5, lines 25 to 30).

Alternatively/additionally, the system of the instant invention may predict, based on a derived toileting or voiding schedule, when an individual is likely to experience a

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Reply to Office Action of June 8, 2010

Attorney Docket: P71951US0

wetness event which meets predefined criteria for manual checking (page 6, lines 5 to 7). Further, the instant invention may be utilized to characterize a wetness event in such a way that the processing means may classify a possible form of incontinence suffered by a patient being monitored, where the form of incontinence may be, for example, urinary, fecal, dribble, stress, overflow, urge, mixed urinary (MUI), total and functional incontinence to name a few. Lingering wetness may also be recognized (page 6, lines 11 to 15). Each of these determinations are made possible because of the mathematical model derived by the system, based on sensor signals previously obtained over time from absorbent articles being monitored by the system. This is not the case in Panopoulos.

In fact, Panopoulos teaches against these determinations and use of mathematical models for making those determinations, since Panopoulos is directed to *avoiding* any lingering wetness in the diaper by alerting caregivers *as soon as wetness or fecal exudate is detected*, so that the diaper can be immediately changed, thereby improving the sanitary and hygienic environment for the wearer.

In view of the foregoing, there is no motivation within Panopoulos or within Bergman to provide a system in which an algorithm applies sensor signals to a mathematical model, which has been pre-determined by the system based on previously received sensor signal data, for characterizing a wetness event. Rather, Panopoulos is merely aiming to identify wetness events and provide a system for alerting a caregiver.

The additional features as described in Panopoulos permit caregivers to record additional information which can be manually inspected, or to detect disease or other abnormalities, or to collect stools and the like, or to apply a salve or ointment. However, Panopoulos does not teach the features that are built into the design of the systems that are utilized by logic circuits to take sensor data and devise a mathematical model using sensor signal data, which model can then be solved to characterize wetness events occurring in an absorbent article. Rather, Panopoulos merely utilizes algorithms, look up tables, and calculations or formulas to convey wetness alerts to Nurse Remote Wand units and to patients' databases.

Appl. No. 11/797,352
Reply to Office Action of June 8, 2010

Attorney Docket: P71951US0

In view of the foregoing, Applicant respectfully submits that the invention as presently claimed is not obvious in view of Bergman when considered alone or in combination with the disclosure of Panopoulos. Rather, Applicant submits that the disclosure of Panopoulos teaches away from the invention as claimed in the instant application.

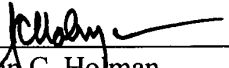
Therefore, the newly presented claims are not obvious over cited references and the rejection under 35 U.S.C. § 103 has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 103 is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Date: December 6, 2010
(202) 638-6666
400 Seventh Street, N.W.
Washington, D.C. 20004
Atty. Dkt. No.: P71951US0

By 
John C. Holman
Registration No. 22,769



BFW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation No.: 6338

Frederick BERGMAN et al.

Attorney Docket No.: P71951US0

Serial No. 11/797,352

Group Art Unit: 3761

Filed: May 2, 2007

Examiner: Ginger T. CHAPMAN

For: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

PETITION FOR EXTENSION OF TIME

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Petition for Extension of Time for a three-month period. This Petition for Extension of Time is being concurrently filed with a Response. A Credit Card Payment Form in the amount of \$555.00 is enclosed. If the Examiner should find a discrepancy in the fees owed, please debit or credit Deposit Account No. 06-1358.

Respectfully submitted,

JACOBSON HOLMAN, PLLC

By

John C. Holman
John C. Holman
Reg. No. 22,769

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666
Date: December 6, 2010

12/07/2010 SMOHANME 00000026 11797352

01 FC:2253

555.00 OP

PTO/SB/06 (07-06)

Approved for use through 1/31/2007. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PATENT APPLICATION FEE DETERMINATION RECORD Substitute for Form PTO-875					Application or Docket Number 11/797,352		Filing Date 05/02/2007		<input type="checkbox"/> To be Mailed	
APPLICATION AS FILED – PART I										
(Column 1)			(Column 2)			SMALL ENTITY <input checked="" type="checkbox"/> OR		OTHER THAN SMALL ENTITY		
FOR	NUMBER FILED	NUMBER EXTRA	RATE (\$)	FEE (\$)	OR	RATE (\$)	FEE (\$)			
<input type="checkbox"/> BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> SEARCH FEE (37 CFR 1.16(k), (l), or (m))	N/A	N/A	N/A			N/A				
<input type="checkbox"/> EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A				
TOTAL CLAIMS (37 CFR 1.16(i))	minus 20 =	*	X \$ =		OR	X \$ =				
INDEPENDENT CLAIMS (37 CFR 1.16(h))	minus 3 =	*	X \$ =			X \$ =				
<input type="checkbox"/> APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).									
<input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))										
* If the difference in column 1 is less than zero, enter "0" in column 2.										
APPLICATION AS AMENDED – PART II										
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	12/06/2010	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)	
Total (37 CFR 1.16(i))	*	61	Minus	** 79	=	0	OR	X \$ =		
Independent (37 CFR 1.16(h))	*	1	Minus	*** 7	=	0	OR	X \$ =		
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE	0	OR	TOTAL ADD'L FEE		
(Column 1)			(Column 2)			SMALL ENTITY OR		OTHER THAN SMALL ENTITY		
AMENDMENT	CLAIMS REMAINING AFTER AMENDMENT	HIGHEST NUMBER PREVIOUSLY PAID FOR	PRESENT EXTRA	RATE (\$)	ADDITIONAL FEE (\$)	OR	RATE (\$)	ADDITIONAL FEE (\$)		
Total (37 CFR 1.16(i))	*	Minus	**	=	X \$ =	OR	X \$ =			
Independent (37 CFR 1.16(h))	*	Minus	***	=	X \$ =	OR	X \$ =			
<input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))										
<input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))										
					TOTAL ADD'L FEE	OR	TOTAL ADD'L FEE			
* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.										
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".										
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".										
The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1.										

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Legal Instrument Examiner:
/ROLITA WIMBUSH/



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

136 7590 03/07/2011
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC 20004

EXAMINER

CHAPMAN, GINGER T

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 03/07/2011

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	05/02/2007	Frederick Bergman	P71951US0	6338

TITLE OF INVENTION: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	06/07/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

136 7590 03/07/2011
JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	05/02/2007	Frederick Bergman	P71951US0	6338

TITLE OF INVENTION: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	06/07/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
CHAPMAN, GINGER T	3761	604-361000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
 United States Patent and Trademark Office
 Address: COMMISSIONER FOR PATENTS
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	05/02/2007	Frederick Bergman	P71951US0	6338

EXAMINER
CHAPMAN, GINGER T

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 03/07/2011

136 7590 03/07/2011
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC 20004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
 (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 387 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 387 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No.	Applicant(s)	
	11/797,352	BERGMAN ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/06/2010.

2. ☒ The allowed claim(s) is/are 1,3-42,57-74,80 and 81.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of the:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. ____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date ____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material	5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413), Paper No./Mail Date ____ 7. <input type="checkbox"/> Examiner's Amendment/Comment 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other ____
---	--

	/Tatyana Zalukaeva/ Supervisory Patent Examiner, Art Unit 3761
--	---

Notice of References Cited	Application/Control No. 11/797,352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.	
	Examiner Ginger T. Chapman	Art Unit 3761	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,680,590	10-1997	Parti, Michael	703/2
*	B	US-7,693,697	04-2010	Westenskow et al.	703/11
*	C	US-6,093,869	07-2000	Roe et al.	604/361
*	D	US-4,356,818	11-1982	Macias et al.	128/886
*	E	US-5,074,317	12-1991	Bondell et al.	128/886
*	F	US-2005/0131663	06-2005	Bangs et al.	703/011
*	G	US-2006/0253296	11-2006	Liisberg et al.	705/001
*	H	US-7,454,314	11-2008	Holland et al.	702/182
*	I	US-2005/0043894	02-2005	Fernandez, Dennis S.	702/019
*	J	US-6,175,752	01-2001	Say et al.	600/345
*	K	US-5,262,944	11-1993	Weisner et al.	600/300
*	L	US-2007/0288414	12-2007	Barajas et al.	706/46
*	M	US-6,603,403	08-2003	Jeutter et al.	340/604

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 11/797,352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.	
	Examiner Ginger T. Chapman	Art Unit 3761	Page 2 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,103,835	04-1992	Yamada et al.	600/547
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			


FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
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	P					
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	R					
	S					
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NON-PATENT DOCUMENTS

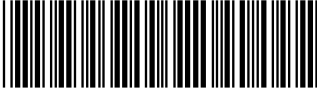
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	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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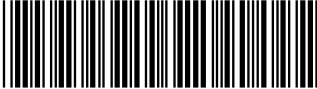
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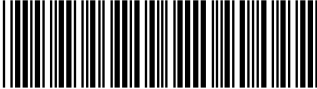
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
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✓	Rejected
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-	Cancelled
÷	Restricted

N	Non-Elected
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O	Objected


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Issue Classification 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
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ORIGINAL						INTERNATIONAL CLASSIFICATION													
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CROSS REFERENCE(S)																			
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/Ginger T Chapman/ Examiner.Art Unit 3761 (Assistant Examiner)	03/02/2011 (Date)	Total Claims Allowed: 61	
/Tatyana Zalukaeva/ Supervisory Patent Examiner.Art Unit 3761 (Primary Examiner)	03/03/2011 (Date)	O.G. Print Claim(s) 1	O.G. Print Figure 1

Search Notes 	Application/Control No. 11797352	Applicant(s)/Patent Under Reexamination BERGMAN ET AL.
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SEARCHED			
Class	Subclass	Date	Examiner
604	361	5/28/2010	GC
604	361, 385.01	3/2/2011	GC
702	177, 180, 181, 188, 189	3/2/2011	GC
703	11, 16, 17	3/2/2011	GC
705	2, 3	3/2/2011	GC

SEARCH NOTES		
Search Notes	Date	Examiner
inventor's names search eDAN, EAST	5/28/2010	GC
EAST search attached	5/28/2010	GC
inventors' names searches PatentScope (WIPO/IPDL)	3/2/2011	GC
forward and backward cite relevant references	3/2/2011	GC
EAST search attached, see search history for keywords and text searches	3/2/2011	GC

INTERFERENCE SEARCH			
Class	Subclass	Date	Examiner
604	361	3/2/2011	GC

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EAST Search History

EAST Search History**EAST Search History (Prior Art)**

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S18	8	S17 and ((sensor\$) and ((user adj interface) or (GUI)))	US-PGPUB; USPAT; EPO; DERWENT	OR	OFF	2010/05/28 17:56

EAST Search History

S17	14	(US-20070270774-\$ or US-20050033250-\$ or US-20040220538-\$ or US-20050046578-\$ or US-20030011479-\$.did. or (US-7522061-\$ or US-7295125-\$ or US-6246330-\$ or US-5902296-\$ or US-4507121-\$.did. or (WO-2007128038-\$ or WO-2006047815-\$ or WO-9614813-\$.did. or (WO-2007128038-\$.did.	US-PGPUB; USPAT; EPO; DERWENT	OR	OFF	2010/05/28 17:55
S16	2	("20030011479").did.	US-PGPUB; DERWENT	OR	ON	2010/05/28 17:55
S15	3	("2003011479").did.	US-PGPUB; DERWENT	OR	ON	2010/05/28 17:54
S14	9	("5902296" "4507121" "2003011479" "20050046578").did.	US-PGPUB; USPAT; DERWENT	OR	ON	2010/05/28 17:53
S13	8	S12 and ((user adj interface) or (GUI))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:49
S12	200	S10 and (sensor\$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:49
S11	17	S10 and (processor and sensor\$1)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:49
S10	486	604/361.ccls.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:48
S9	24	S2 or S3 or S4 or S5 or S6 or S7 or S8	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:45
S8	2	bergman-ari\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:44

EAST Search History

S7	2	eitzen-guy\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:44
S6	2	rodde-maria\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:44
S5	2	guibert-remi\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:44
S4	2	weinstock-daniel\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:44
S3	14	barda-david\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:43
S2	10	bergman-frederick\$.in.	US-PGPUB; USPAT; FPRS; EPO; JPO; DERWENT	OR	ON	2010/05/28 17:43
S1	2	"20070270774".did.	US-PGPUB; USPAT; DERWENT	OR	ON	2010/04/13 23:49

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L37	1	((input) and (processor controller) and (user adj interface) and (algorithm) and (mathematical adj model) and (sensor) and (signal) and (variable variables) and (patient hospital)).clm.	US-PGPUB; USPAT; UPAD	OR	ON	2011/03/02 18:05

3/2/2011 6:36:22 PM

C:\Documents and Settings\GChapman\My Documents\EAST\Workspaces\11 797 352.wsp

FORM PTO-1449 (Modified)

Sheet 2 of 3

JACOBSON HOLMAN PLLC
 400 SEVENTH STREET, N.W.
 WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P71951US0
 SERIAL NO. 11/797,352
 APPLICANT(S): BERGMAN et al.

GROUP ART UNIT: 3761
 FILING DATE: May 2, 2007
 TODAY'S DATE: September 30, 2008

	BN	2002/0003478	01/10/02	Zhao et al.			
	BO	2003/0011479	01/16/03	Bluteau			
	BP	2003/0060789	03/27/03	Shapira et al.			
	BQ	2004/0220538	11/04/04	Panopoulos			
	BR	2005/0046578	03/03/05	Pires			
	BS	2005/0156744	07/21/05	Pires			
	BT	2006/0139165	06/29/06	Bader			

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES) (NO)
	CA	2 361 132	05/07/02	Canada			
	CB	1 047 033	10/25/00	Europe			
	CC	1 063 624	12/27/00	Europe			
	CD	1 567 998	08/31/05	Europe			Abstract only
	CE	2 733 146	10/25/96	France			Abstract
	CF	198 37 678	03/02/00	Germany			Abstract
	CG	WO 97/42613	11/13/97	PCT			
	CH	WO 02/101679	12/19/02	PCT			
	CI	WO 2004/034929	04/29/04	PCT			
	CJ	WO 2004/049969	06/17/04	PCT			
	CK	WO 100763	11/25/04	PCT	WO 2004/100763		
Change(s) applied to document,	CL	WO 2005/107580	11/17/05	PCT			
	CM	WO 2006/047815	05/11/06	PCT			

Change(s) applied
to document,

/S.R.R./

4/19/2011

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	DA	Wu et al. "Odor-Based Incontinence Sensor." Robotics Institute, School of Computer Science, 2000, Pages 63-68.
	DB	"Wet-Sense Monitoring System." Technology for Long Term Care. 02/19/06. www.techforlrc.org/lrc.cfm?pageid=157&product=820&careissue=3 .
	DC	"SenseSoft." Sensible Solutions. www.sensible-solutions.se/index.php?option=com_content&task=view&id=25&Itemid=36 .
	DD	"Incontinence event data logger." Date Logger. 07/08/00. www.medphys.ucl.ac.uk/udlh-compinst/instrumentation/past/data%20logger.htm .
	DE	"Roke Manor Research Develops Wireless Patient Monitor." Roker Manor Research Limited. April 30, 2003. www.roke.co.uk/press/index.php?id=53&format=print .

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C./

FORM PTO-1449 (Modified)

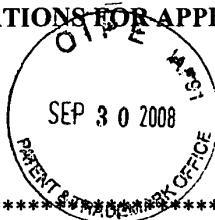
Sheet 1 of 3

JACOBSON HOLMAN PLLC
400 SEVENTH STREET, N.W.
WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P71951US0
SERIAL NO. 11/797,352
APPLICANT(S): BERGMAN et al.

GROUP ART UNIT: 3761
FILING DATE: May 2, 2007
TODAY'S DATE: September 30, 2008



U.S. PATENT DOCUMENTS

Change(s) applied
to document,
/S.K.K./
4/20/2011

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	4,356,818	11/02/82	Macias et al.			
	AB	4,507,121	03/26/85	Leung			
	AC	4,539,559	09/03/85	Kelly et al.			
	AD	4,977,906	12/18/90	Di Scipio			
	AE	5,036,859	08/06/91	Brown			
	AF	5,264,830	11/23/93	Kline et al.			
	AG	5,416,469	05/16/95	Colling			
	AH	5,568,128	11/22/96	Nair			
	AI	5,537,095	07/16/96	Dick et al.			
	AJ	5,570,082	10/29/96	Mahgerefteh et al.			
	AK	5,557,263	09/17/96	Fisher et al.			
	AL	5,760,694	06/02/98	Nissim et al.			
	AM	5,790,036	08/04/98	Fisher et al.			
	AN	5,838,240	11/17/98	Johnson			
	AO	5,902,296	05/11/99	Fluyeras			
	AP	5,959,535	09/28/99	Remsburg			
	AQ	6,091,336	07/18/00	Zand et al.			
	AR	6,093,869	07/25/00	Roe et al.			
	AS	6,097,297	08/01/00	Fard			
	AT	6,149,636	11/21/00	Roe et al.			
	AU	6,246,330	06/12/01	Nielsen			
	AV	6,292,102	09/18/01	Smith			
	AW	6,384,728	05/07/02	Kanor et al.			
	AX	6,384,296	05/07/02	Roe et al.			
	AY	6,433,695	08/13/02	Kai et al.			
	AZ	6,544,200	04/08/03	Smith et al.			
	BA	6,559,772	05/06/03	Zand et al.			
	BB	6,573,837	06/03/03	Bluteau			
	BC	6,603,403	08/05/03	Jeutter et al.			
	BD	6,774,800	08/10/04	Friedman et al.			
	BE	6,876,303	04/05/05	Reeder et al.			
	BF	6,916,968	07/12/05	Shapira et al.			
	BG	7,049,969	05/23/06	Tamai			
	BH	7,053,781	05/30/06	Haire et al.			
	BI	7,071,830	07/04/06	Sahlberg et al.			
	BJ	7,141,715	11/28/06	Shapira			
	BK	7,176,344	02/13/07	Gustafson et al.			
	BL	7,221,279	05/22/07	Nielsen			
	BM	7,250,547	07/31/07	Hofmeister			

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.C./

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, Virginia 22313-1450
 or **Fax** (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

136 7590 03/07/2011
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC 20004



Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

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I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	05/02/2007	Frederick Bergman	P71951US0	6338

TITLE OF INVENTION: INCONTINENCE MANAGEMENT SYSTEM AND DIAPER

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$755	\$300	\$0	\$1055	06/07/2011
06/07/2011 AWONDAF2 00000023 11797352						
EXAMINER	ART UNIT	CLASS-SUBCLASS				
CHAPMAN, GINGER T	3761	604-361000				
			01 FC:2501	755.00 OP		
			02 FC:1504	300.00 OP		

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer Number is required.

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively,
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 JACOBSON HOLMAN PLLC

2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

FRED BERGMAN HEALTHCARE PTY LTD.

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Melbourne VIC 3004, AUSTRALIA

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☒ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☒ Issue Fee (755)
☒ Publication Fee (No small entity discount permitted) (300)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☒ Payment by credit card. Form PTO-2038 is attached. (1055)
☒ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number 06-1358 (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature

John C. Holman
 Typed or printed name John C. Holman

Date June 6, 2011

Registration No. 22,769

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/797,352	07/12/2011	7977529	P71951US0	6338

136 7590 06/22/2011
 JACOBSON HOLMAN PLLC
 400 SEVENTH STREET N.W.
 SUITE 600
 WASHINGTON, DC 20004

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
 (application filed on or after May 29, 2000)

The Patent Term Adjustment is 823 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

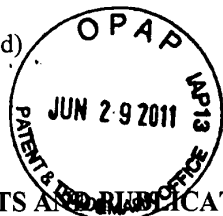
Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Application Assistance Unit (AAU) of the Office of Data Management (ODM) at (571)-272-4200.

APPLICANT(s) (Please see PAIR WEB site <http://pair.uspto.gov> for additional applicants):

Frederick Bergman, Caulfield, AUSTRALIA, Deceased;
 Ari Bergman, Caulfield, AUSTRALIA, Legal Representative;
 David Albert Barda, Docklands, AUSTRALIA;
 Daniel Weinstock, Caulfield South, AUSTRALIA;
 Remi Guibert, Mount Martha, AUSTRALIA;
 Maria C. Rodda, Mount Eliza, AUSTRALIA;
 Guy Eitzen, Wheelers Hill, AUSTRALIA;

PTO/SB/08a (modified)

Sheet 1 of 1



JACOBSON HOLMAN PLLC
400 SEVENTH STREET, N.W.
WASHINGTON, D.C. 20004-2201

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.: P71951US0
SERIAL NO. 11/797,352
APPLICANT(S): BERGMAN, et al

GROUP ART UNIT: 3761
FILING DATE: May 2, 2007
TODAY'S DATE: June 29, 2011

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	PUBLICATION DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,568,128	October 22, 1996	Nair			
	AB						
	AC						
	AD						
	AE						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION (YES) (NO)
	BA						
	BB						
	BC						
	BD						
	BE						

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	CA	
	CB	
	CC	
	CD	

EXAMINER	DATE CONSIDERED
----------	-----------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s)



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

BERGMAN, et al

Group Art Unit: 3761

Serial No.: 11/797,352

Examiner: Ginger T. Chapman

Filed: May 2, 2007

Confirmation No: 6338

For: INCONTINENCE MANAGEMENT
SYSTEM AND DIAPER

PRIOR ART OF RECORD

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The above captioned application has been found allowable and the issue fee has been paid. It has just now come to counsel's attention that there has been an official letter on an equivalent application in Europe which has brought to the applicant's attention U.S. patent 5,568,128.

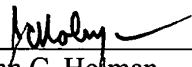
The Australian attorney believes that this reference is no more pertinent than the references already cited by the Examiner. In an abundance of caution a copy of this U.S. patent is attached and is requested that it be placed in the record of this serial number.

U.S. Patent Application No.: 11/797,352
Page 3

It is understood that this U.S. patent will not be considered by the Examiner but rather will be placed in the file history. It is requested that this transmittal and enclosure be so placed for full and complete disclosure.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: 
John C. Holman
Reg. No. 22769

400 Seventh Street, N.W.
Washington, D.C. 20004-2201
(202) 638-6666
Atty. Docket: P71951US0
Date: June 29, 2011

Enclosure: copy U.S. patent 5,568,128